INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 1, No. 29
July 27, 2015

IN THIS ISSUE

Bard Hit With Warning Letter Over Unapproved Devices, Quality Issues

The FDA has come down on C.R. Bard for not addressing quality systems and medical device reporting observations at two of its plants.

In a far-ranging July 13 warning letter, the FDA details problems found at the Bard Peripheral Vascular facility Tempe, Ariz., and a plant in Queensbury, N.Y., during separate inspections in 2014 and the beginning of this year. The inspectors noted their findings in Form 483s, and the FDA deemed many of the company's responses inadequate.

According to the warning letter, Bard is manufacturing two recovery cone removal systems without the required clearance or approval at its Tempe facility. Model RC-15, which is intended to percutaneously remove certain inferior vena cava filter delivery systems, is not included as part of the clearances for any of these filters.

(See **Bard**, *Page 2)*

Unannounced Inspections Await Chinese Device Manufacturers

Devicemakers in China can expect surprise inspections from that country's Food and Drug Administration starting Sept. 1, according to recently released guidance.

The CFDA says companies can expect teams of investigators who will document the inspection process, identify problems and relevant evidence, examine findings and make recommendations for improvement.

The guidance follows a May 18 notice that provided information on the inspections. "Since the inspection regulation is supposed to take place effective Sept. 1, this guidance is coming about six weeks ahead, which should give the industry sufficient preparation," says Helen Chen, director and partner at L.E.K. Consulting. She adds that the government has been looking to address medical product quality issues. "The introduction of the unannounced inspections is a significant new step in this process."

(See **China**, *Page 4)*

Bard, *from Page 1*

The agency acknowledges the company has submitted *in vivo* and *in vitro* testing demonstrate use of the model for the removal of these filters.

The letter also advises Bard that the Recovery Cone Removal System, Model FBRC, is adulterated because the company doesn't have an approved PMA or IDE application for the product. Although the company lists the model as a Class I surgical snare, the FDA says there is evidence that it is intended for uses that are different from legally marketed devices.

"Devices of this type usually consist of a non-powered, hand-held, or hand-manipulated device that is either reusable or disposable, which are intended to be used in general surgical procedures," according to the letter.

Bard is marketing this model for the percutaneous removal of IVC filters, a specialized intended use, within a defined medical specialty: cardiovascular surgery.

Because of this intended use, it is not exempt from premarket notification.

The FDA says Bard has yet to submit a response about violations and advises the company to stop commercial distribution of the devices for unapproved uses.

Complaints

Inspectors also cited Bard for not establishing and maintaining procedures for receiving, reviewing and evaluating complaints. The letter refers to instances in which device malfunction reports should have been filed as serious injuries and, in one case, death, occurred.

In addition, there were at least 10 patients who underwent unsuccessful surgical procedures to remove an IVC filter. The complaint files do not contain enough information to conduct an adequate investigation, the warning letter notes, such as potential patient complications due to leaving the filter longer than expected.

Bard submitted 11 separate responses — six from the Queensbury plant and five from the Tempe facility — but the FDA called them insufficient.

A Jan. 26 response from the Tempe facility cited clerical errors and noted it had "opened a CAPA to track training and determination of root cause with corrective and preventive actions," according to the warning letter. However, the FDA said this doesn't ensure that complaints are evaluated adequately.

The letter also knocks the New York facility for failing to validate a manufacturing process that inspection and testing could not fully verify.

The agency found Bard's response is partially adequate, given that the company has made progress validating the cleaning processes for Denali filters and the Simon nitinol filters. However, a follow-up inspection will be necessary to fully evaluate Bard's actions.

Also, while the company has performed "exhaustive extraction testing" of the Denali filter made by one of its suppliers, the other uses a different manufacturing process, processing agents and equipment. The FDA wants Bard should perform similar testing on products from that supplier.

MDR Problems

The FDA also chides Bard for not providing an adequate response for MDR violations at the Tempe facility. In one instance, a complaint described a malfunction of a long-term implant, but Bard failed to rule out that a recurrence of the problem was unlikely to result in serious injury or death.

In a Securities & Exchange Commission filing, Bard acknowledged receiving the letter and promised to take action.

To read the warning letter, visit www.fdanews.com/072715-Bard-warning-letter.pdf.
— Elizabeth Hollis

St. Jude Medical Inks $3.4B Deal to Buy Thoratec

The megamerger trend in the medical device industry continues unabated, with St. Jude Medical offering to acquire Thoratec in an all-cash transaction valued at about $3.4 billion.

The buy will strengthen St. Jude's heart failure portfolio, as Pleasanton, Calif.-based Thoratec markets the HeartMate II left ventricular assist system and the paracorporeal ventricular assist device. In early July, Thoratec's HeartMate percutaneous heart pump received CE mark approval, and the company has received an unconditional FDA nod for the IDE study of the device.

St. Jude's heart failure options currently include the Quadripolar CRT-D and CRT-P technologies, multipoint pacing CRT technology, remote monitoring capabilities and CardioMEMS HF system.

In addition, St. Jude will gain access to markets totaling more than $1 billion, according to a statement announcing the deal.

Analysts React

In a note, Leerink analyst Danielle Antalffy sees the acquisition as positive, labeling it as highly strategic and making St. Jude a potential big player in a high-growth market.

Despite the positives, the merger agreement includes a 30-day "go-shop" period, during which Thoratec may seek alternative proposals from third parties. While the transaction is expected to close in the fourth quarter, some analysts see the potential for another suitor to come into the picture.

Analysts with Wells Fargo Securities say the go-shop period is not common, adding that Medtronic, Abbott and Johnson & Johnson could be possible bidders. They add that a potential bidder may wait as long as possible to make an offer to see how Thoratec rival HeartWare's MVAD implant is progressing.

HeartWare announced July 20 that had started a CE mark clinical trial for the MVAD system. It also has submitted an IDE application to the FDA.

In 2009, the Federal Trade Commission scuttled plans for Thoratec's proposed $282 million acquisition of HeartWare, saying it would reduce competition in the U.S. market for left ventricular devices.

Not everyone thinks that another company is waiting in the wings to make a higher offer. Ben Andrew of William Blair thinks the deal will go through.

Quarterly Numbers

Word of the deal came as St. Jude announced its second quarter results. The company, which had net sales of $1.410 billion, a 3 percent decrease compared with $1.448 billion during the prior year quarter, saw strength in its atrial fibrillation and neuromodulation areas, which came in at $279 million and $118 million, respectively.

However, it saw decline in total cardiac rhythm management sales — including implantable cardioverter defibrillators and pacemakers — which came in at $670 million, down 9 percent from the prior year quarter.

After adjusting for the impact of foreign currency, sales were down 1 percent.

The St. Jude-Thoratec deal comes after Becton, Dickinson & Co. closed its more $12 billion buyout of CareFusion in March and Medtronic wrapped its nearly $50 billion deal to acquire Covidien.

Last month, Zimmer completed its $14 billion buyout of Biomet following clearance from the FTC.

Pfizer's proposed $17 billion buyout of Hospira is being scrutinized by EU and U.S. competition authorities, and Wright Medical is awaiting the FTC's blessing for its Tornier buy.
— Elizabeth Hollis

China, *from Page 1*

Inspections may be launched based on complaints or credible reports of quality and safety risks, an adverse event report, serious record-keeping problems or violations of quality management standards.

The government has several options for dealing with companies with serious problems.

"The violators can have their production and sales licenses temporarily revoked, and thus be unable to continue their business," Chen says. "They can also be reported to the Public Security Bureau and publicly shamed via press conferences. There are no fees or financial compensations specifically mentioned."

Once any risks have been eliminated, actions taken against the company will be lifted, the guidance says.

Adverse Event Reports

The CFDA also has released details on 41,018 device adverse event reports, including 98 reported deaths in 2014, an 18.6 percent increase over the 2013 total. Class III medical equipment accounted for 42.7 percent of adverse event reports, Class II, 36.7 percent, and Class I, 18.2 percent.

The report lists medical polymer materials, injection equipment and medical materials and dressing as the top product categories for adverse events that were reported. — Elizabeth Hollis

Venture Capitalists Eye Medical Device Industry

Private medical device companies had a huge second quarter in terms of funding from investors, taking in more than $800 million. That figure represents an increase of about 70 percent over the first quarter of the year, according to a report from PricewaterhouseCoopers and the National Venture Capital Association.

For the two quarters, medical device companies have taken in about $1.29 billion — slightly ahead of the halfway mark of 2014, when the total stood at $1.26 billion, according to the PwC/NVCA *MoneyTree* report based on data from Thomson Reuters. During the second quarter of 2014, medtech companies reeled in $667.2 million in funding.

Across the board, private companies are seeing a rise in funding from VC firms. "Driven by a strengthening fundraising environment, the venture ecosystem deployed more capital to the innovation economy in the second quarter than any period in the last 15 years. While this uptick can be partly attributed to non-traditional investors joining funding rounds, venture continues to lead the way in deploying capital to the most promising new technologies and companies," says Bobby Franklin, president and CEO of NVCA, in a prepared statement.

Among devicemakers, Calhoun Vision, a Pasadena, Calif.-based company that is developing a light adjustable intraocular lens, led the pack. In June, the company announced it had raised nearly $69 million in financing — $52 million in new financing, and an additional $17 million in debt conversion. The company plans to use the proceeds to advance its lens which is in Phase III trials.

The next largest financing went to San Jose, Calif.-based Outset Medical, which reeled in $51 million, according to the company.

Outset markets a simplified dialysis machine that it hopes to bring into patients' homes. The FDA recently approved an IDE application for a trial in this setting.

Overall, second quarter investments in the life sciences sector — biotechnology and medical devices combined — accounted for approximately $3.1 billion going into 201 deals, a 41 percent increase in dollars, but flat in terms of deals, versus the first quarter of the year.
— Elizabeth Hollis

BD Hit With Antitrust Lawsuit By Georgia-Based Health System

A Georgia-based health system has lodged a complaint against Becton, Dickinson and Co., accusing the medical products manufacturer of stifling competition in the hypodermic syringe and intravenous catheter markets.

In a suit filed July 17, the Southeast Georgia Health System maintains that BD has charged above-competitive prices while commanding more than 70 percent of market share by revenue for the sale of syringes to acute care providers. Covidien, its next closest competitor, has about 17 percent.

Despite this market domination, the plaintiff says BD "has lethargically and unhelpfully made only minor and ineffective changes to its conventional syringes," with its bestselling manual safety syringe earning a rating of "unacceptable" from the Emergency Care Research Institute, a testing laboratory.

BD continues to make these unsafe syringes despite federal law, which has mandated practices to reduce wounds caused by needle jabs, the suit says. Needlestick injuries put healthcare providers at greater risk for contracting HIV and hepatitis B and C.

Potential Competitors

Other companies, including Retractable Technologies, have tried to overcome BD's "dangerous lethargy" by producing syringes that have received high marks from ECRI, the complaint adds.

BD's alleged tactics include exclusionary bundled rebates, penalty contracts and sole-source contracts, theft of Retractable's technology, six years of competitive deception and false advertising, and elimination of a rival through acquisition, according to court documents.

The health system maintains BD used similar tactics to gain a monopoly in the IV catheter arena.

The plaintiff further points out that the U.S. Justice Department has compelled the company to enter two consent decrees. These decrees, plus jury awards to Retractable and an acquisition of a large rival, have cost BD about $485.6 million, the complaint alleges.

In January, a judge in the U.S. District Court for the Eastern District of Texas ruled that BD must pay Retractable more than $350 million for attempting to monopolize the safety syringe market.

RTI filed suit in May 2010, alleging that ads touting BD's needles as the sharpest in the world were false and misleading. It also contended that BD falsely told customers that its syringes saved medication versus RTI's products (*IDDM*, Jan. 23).

Class Action

In the current case, the health system is seeking a class action lawsuit against BD, representing U.S.-based acute care providers that bought the company's hypodermic syringes on or after July 17, 2011, through cost-plus distributor contracts. These contracts forced the distributors "to pass on all of Becton's monopoly pricing," according to court documents.

The health system also is seeking a similar action for those that purchased BD's IV catheters.

The health system also is asking the court to find BD's actions in violation of the Sherman Act and is seeking treble actual damages, attorneys' fees and pre- and postjudgment interest.

"We plan a vigorous defense for this case," Troy Kirkpatrick, BD's director of public relations, tells *IDDM*.

Glynn-Brunswick Hospital Authority, Trading as Southeast Georgia Health System, Georgia Health System, Inc., v. Becton, Dickinson and Company was filed in the U.S. District Court for the Southern District of Georgia.
— Elizabeth Hollis

FDA Seeks Feedback On Patient Labeling

Patient labeling for medical devices will take center stage at a September FDA workshop as the agency considers updating industry guidance on the topic.

Scheduled for Sept. 29 and 30 at the FDA's White Oak campus in Silver Spring, Md., the workshop will focus on the content, testing, use, access, human factors considerations, emerging media formats, and promotion and advertising of patient labeling, according to a *Federal Register* notice. The agency expects to hear from advocacy groups, academic and professional organizations, industry, standards bodies and government agencies.

Patient labeling includes information intended for a lay audience and is supplied in formats such as brochures, leaflets, user manuals, video or audio recordings and physical or online media. It is intended to ensure that devices are used safely and effectively. The agency previously issued guidance on patient labeling in April 2001 that suggested content, including descriptive and operating information.

In advance of the workshop, the FDA is seeking feedback on the following issues: current trends in device labeling; risk and adverse outcomes associated with device labeling; labeling challenges that affect clearance or approval; opportunities for stakeholders to work together to address labeling needs; and potential changes to current guidance and standards to enhance labeling.

Interested parties may comment through Oct. 30, 2015.

Read the *Federal Register* notice at www.fdanews.com/072715-labeling-workshop.pdf.
— Elizabeth Hollis

MHRA Details Thinking Regarding Remanufacture of Single-Use Devices

The UK's Medicines and Healthcare products Regulatory Agency is advising companies that remanufacture single-use medical devices that they are subject to the same adverse event reporting requirements as original equipment manufacturers.

The requirement is part of draft guidance published July 20, which takes into account a two-year review that assessed manufacturers' technical, regulatory and clinical processes. Companies have indicated to the MHRA that they want to put their products on the UK market, as the remanufacturing process has been utilized in other countries for a number of years.

Among other things, the agency wants remanufacturers to demonstrate that their products meet all appropriate criteria of the relevant medical devices directive in terms of performance and safety. A refurbished device's labeling must state that the device is remanufactured and include the OEM's name and product serial number. Remanufacturers also should demonstrate compliance with ISO 14971 – *Risk management for medical devices* to identify all possible risks and mitigation strategies for the device.

Remanufacturers also must continuously monitor for any changes the OEM makes to the product, the guidance says. Suggested tactics include:

- Continuous market observations or safety information published by the OEM;
- FDA approvals or safety information;
- Safety information from competent authorities;
- Information from end users;
- Incoming goods inspection for all devices;
- Electrical, material, performance and safety assessments conducted on all devices during remanufacturing; and
- Manufacturing and outgoing goods inspections for all devices.

Remanufacturers also are responsible for managing any product safety notification or recall an OEM has implemented that affects one of their devices, the MHRA says.

If the device fails to meet safety and efficiency expectations, or there is an indication that the product has been remanufactured or reprocessed at a different facility, the company must dispose of that item, according to the draft document. Remanufacturers also are responsible for keeping track of how many times a device is refurbished and reused.

Remanufacturers should have technical documents on hand to show their device conforms to the requirements of the relevant directive. This documentation should be on file for at least five years, or for an implantable device 15 years after the last product was placed on the market.

Remanufacturers of single-use devices, providers of medical devices, CEOs and managers of organizations where these devices may be used and healthcare professionals are encouraged to participate in a survey posted on the MHRA's website. The agency will accept feedback until Sept. 1, 2015. Final guidance is expected by the end of the year.

To view the draft guidance, visit www.fdanews.com/072715-MHRA-single-use.pdf.
— Elizabeth Hollis

Senate Bill Aims to Streamline Combination Products Review

A bipartisan group of lawmakers introduced legislation aimed at clarifying the review process for combination products.

Sens. Johnny Isakson (R-Ga.), Robert Casey (D-Pa.), and Pat Roberts (R-Kan.) introduced the Combination Product Regulatory Fairness Act of 2015, which would amend language in the Federal Food, Drug and Cosmetic Act related to these products. Isakson says the bill "will eliminate the high level of uncertainty in approval standards that currently exist for innovative companies, both small and large, when deciding to invest in a new product."

(See **Combo,** *Page 8)*

Combo, *from Page 7*

A key provision of the bill, introduced July 17, emphasizes that reviewers may rely on prior findings of safety and effectiveness for a drug product, as well as existing premarket approvals when evaluating a combination product.

Also included in the bill is a proposal for a combination product review plan, detailing the necessary clinical studies, timelines and potential risks for the product. Sponsors could request a pre-CPRP meeting with the FDA to discuss requirements and standards related to the review of product's safety and effectiveness — or substantial equivalence, postmarket modification or good manufacturing practices.

The bill proposes a 60-day period for the agency to review and either accept or refuse a CPRP. If the agency declines to approve the CPRP, a meeting must take place within 30 days to discuss the level of evidence necessary to ensure a positive determination of safety and effectiveness or substantial equivalence.

In addition, the bill would require the FDA to issue final guidance within two years of enactment describing each center's responsibilities in the review process for combination products. The guidance should detail how each center evaluates evidence development and review under a risk-based approach, dispute resolution, labeling, product usability assessments and human factors testing.

Industry welcomed the lawmakers' efforts. "Combination products — whether device/drug, device/biologic or drug/biologic — represent some of the most innovative treatment options for American patients," AdvaMed President and CEO Stephen Ubl said.

"Unfortunately, FDA's process for determining which of its centers has primary responsibility for reviewing these products, as well as the actual review itself, often lacks predictability and efficiency, delaying patient access to these cutting-edge advancements."

Earlier this year, the FDA released a 46-page draft guidance document intended to clarify a 2013 final rule specifying how combination product manufacturers should meet both device and drug quality regulations and implement streamlined quality systems (*IDDM*, Jan. 30).

To view the bill, visit www.fdanews.com/072715-combination-products-bill.pdf.
— Elizabeth Hollis

Brazilian Authorities Seek Information To Determine Inspection Schedules

A deadline for device companies and makers of in vitro diagnostics in Brazil to submit their responses to a mandatory electronic survey is rapidly approaching.

By Aug. 8, companies need to inform the Agência Nacional de Vigilância Sanitária about the types and class of products they manufacture to help the agency determine the frequency and scope of inspections to assess good manufacturing practices. The regulator announced the request for information June 1.

"They want the information to better plan future inspection activities," explains Marcelo Antunes of SQR Consulting. "There's a new inspection plan procedure being discussed at ANVISA that defines inspection priority based on a risk index, and the information required will be used to determine the complexity of the plant."

Antunes expects fewer inspections focused on high-risk processes and devices.

ANVISA anticipates as many as 1,400 companies will respond to the notice. However, in a July 15 notice, it said only 300 had submitted the required information. Companies failing to do so by the deadline face not getting a GMP certificate.

View the original notice, in Portuguese, at www.fdanews.com/072715-brazil-notice.pdf.
— Elizabeth Hollis

MHRA Urged to Lead International Approach to Device Fee Collections

The UK's Medicines and Healthcare products Regulatory Agency should take the lead in developing a unified international approach for collecting fees related to the regulation of medical devices, a government review of the agency says.

That recommendation comes in the *Triennial Review of the Medicine and Healthcare Products Regulatory Agency*, released last week, the culmination of a Department of Health evaluation of the MHRA's performance. The review took place between November 2014 and May 2015 and incorporated input from stakeholder interviews and workshops, meetings with sector experts, a public call for feedback and analysis of published material and in-house documents.

According to the report, stakeholders hold a generally positive impression of the MHRA. However, challenges remain, including increased competition from other EU regulators for licensing income. "Awareness of new developments with medicines and devices will better enable the agency to anticipate the need for changes to processes or the regulatory framework and to influence international partners," according to the review.

One area in which MHRA may take the lead is developing an approach for applying fees for regulating medical devices. The agency expects to introduce a fee next year related to a medical device company's turnover in the UK. This would provide a secure funding stream, increasing income to more than 90 percent of agency expenditures related to device regulation, the review says.

During the review, stakeholders expressed concern about the potential lack of international consistency in how the fees would be applied. A standardized approach across the EU could prove more effective, eliminating additional burdens, industry argued. With increased revenue from industry, the agency could provide a greater range of expertise when reviewing innovative devices.

The report also calls on the MHRA to continue its work on improving efficiency — something it has approached by cutting costs. It notes, for example, that the agency cut 21 device division staff positions over three years, leading to savings of about US $1.6 million a year by 2013-14. It also eliminated posts on the regulatory side, reflecting a decline in licensing activity.

While the review praises the MHRA's flexibility in the face of changing demands, it also cautions the agency to ensure its employees have the right skills and expertise. This challenge is particularly acute with the complex new technologies and software being used by newer medical devices.

Another area for progress is the agency's technology infrastructure. Currently, it employs a system known as Sentinel to collect information on license applications and adverse event reports for medicines and devices. However, this system has received criticism for not being robust enough. The MHRA is planning to phase in a new system over the next five years.

To review the report, visit www.fdanews.com/072715-MHRA-review.pdf. — Elizabeth Hollis

Medtronic Updates MiniMed IFU In Australia to Prevent Dosing Errors

Medtronic is providing diabetic Australian patients with updated instructions for use for its portable MiniMed 640G insulin pump after identifying the potential for user error.

The action stems from the device's message alert screen not timing out, potential causing confusion. That confusion could lead to incorrect dosing — the over or under delivery of insulin — and cause a serious adverse event, the Therapeutic Good Administration says.

If users don't react promptly to an alert from Bolus Wizard function after inputting blood glucose and carbohydrate intake information, they could administer a bolus dose based on levels that are no longer current, the agency adds.

Medtronic is not removing the pump from the market, but has sent notice to users and healthcare professionals with updated and clarified instructions on how to avoid the problem. — Elizabeth Hollis

BRIEFS

OxyTote Recall Labeled Class I

After reports of serious user injuries and one death, the FDA has determined that a recall of a portable oxygen system regulator from Western Enterprises should be Class I. The company was alerted to the possibility of that the product's compressed gas oxygen cylinder could ignite and explode, and followed up with a recall notice in January saying three events had been received, including the death. In a follow-up letter, the company said that all OxyTOTE, oxyQuik and AirTOTE products are subject to the recall except units marked with a hard stamped "T" on the oxygen cylinder and the brass portion of the regulator body.

Philips, Profound Medical to Collaborate

Royal Philips has signed a joint development agreement to integrate Profound Medical's proprietary transurethral ultrasound ablation technology designed to treat prostate cancer with the Ingenia and Achieva 3T MRI systems. Profound's TULSA technology allows for a single-session procedure and is associated with lower rates of side effects, according to Philips. Profound is expected to release 12-month data from its 30-patient safety and feasibility study, with the goal of obtaining a CE mark and commercialization of TULSA-PRO in Europe and Canada next year.

Stryker to Buy Turkish Bed Maker

Stryker has inked a definitive agreement to acquire Muka Metal in an all-cash transaction. The Turkish company sells hospital beds, stretchers and patient room furniture and accessories. The two firms have had a distribution agreement for Latin America since 2012. The transaction is expected to close in the third quarter. Stryker did not disclose the value of the deal.

Boston Scientific Starts Scaffold Study

Investigators have begun the evaluation of Boston Scientific's first fully resorbable drug-eluting scaffold system in patients with atherosclerotic coronary lesions. The study, which will enroll up to 30 patients, has started accepting subjects at a Melbourne, Australia, facility. The resorbable polymer scaffold incorporates elements from the company's Synergy stent system, including a resorbable polymer and an ultrathin everolimus coating.

St. Jude Medical's Penta Lead Wins FDA Nod

The FDA has approved MR-conditional labeling for St. Jude Medical's Penta 5-column paddle lead for spinal cord stimulation therapy to manage chronic pain. The lead will be available for use with the company's Protégé MRI system in the U.S. The product will become the first marketed five-column paddle lead on the market, allowing patients to safely undergo head and extremity MRI scans, according to St. Jude.

Micell to Study MiStent

Micell Technologies has started enrolling patients in its clinical trial evaluating the MiStent SES sirolimus-eluting stent system for coronary artery disease. The study, which is comparing the device against Essen Technologies' Tivoli stent system, has a primary endpoint of nine-month in-stent late lumen loss. The Durham, N.C., company expects to enroll about 428 patients across 18 clinical sites in China.

FDANEWS

Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

Editor: Elizabeth Hollis
(703) 538-7639
ehollis@fdanews.com

Ad Sales: Jim Desborough
(703) 538-7647
jdesborough@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676
www.fdanews.com

Reporters: Kellen Owings, Jonathon Shacat, Jason Scott
President: Cynthia Carter; **Editor-in-Chief:** Meg Bryant; **Managing Editor:** John Bechtel

Understanding China's New Medical Device Regulations

China completely revised its medical device regulations in 2014, and the changes are beginning to take effect NOW.

These revised regulations touch on many areas: research and development, approval, manufacturing, and distribution of medical devices.

And they affect all devices — those already on the market as well as the ones still in development.

If you want to continue — or begin — to sell your medical devices in China, understanding the new rules is absolutely essential.

To gain mastery of these important regulatory changes, there's no better resource than the new FDAnews management report, **Understanding China's New Medical Device Regulations**.

This report is NOT broad brush coverage. You'll learn real specifics as you work your way through the incredible detail of this report, covering such areas as:

- Changes in the basic requirements for registering a medical device in China. (Some devices — but not all — that once needed to be registered no longer do.)
- CFDA has greater enforcement power to order recalls, terminate sales, freeze imports and, most importantly, issue larger penalties to and even shut down devicemakers.
- CFDA can impose moratoriums on devicemakers that fail to satisfy registration requirements and, in serious cases, even revoke their licenses.
- Revisions to medical device classification rules — including new requirements for registering class I devices.
- And much more

With implementation of the new Chinese rules already under way – and more changes coming — it's very clear that to sell medical devices in China in 2015, you must quickly get up to speed on the new and revised requirements.

Order your copy of **Understanding China's New Medical Device Regulations** TODAY.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/49930
3. **FAX:** +1 (703) 538-7676
4. **MAIL:** FDAnews 300 N. Washington St., Suite 200 Falls Church, VA 22046-3431

☑**Yes!** Please send me ____ copy(ies) of ***Understanding China's New Medical Device Regulations*** at the price of $397 each for the format I've selected:

❑ Print ❑PDF

Name _____

Title _____

Company _____

Address _____

City_____ State _____ Zip code _____

Country _____

Telephone _____

Fax _____

Email _____

METHOD OF PAYMENT

❑ Check enclosed (payable to FDAnews)

❑ Bill me/my company. Our P.O.# _____

❑ Charge my credit card:
❑ Visa ❑ MasterCard ❑ American Express

Credit card no. _____

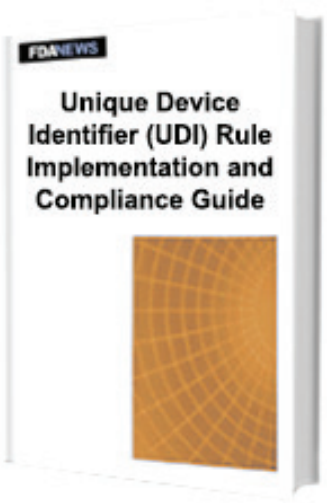
Expiration date _____

Signature _____
(Signature required on credit card and bill-me orders)

Add $10 shipping and handling per book for printed books shipped to the U.S. and Canada, or $35 per book for books shipped elsewhere. Virginia customers add 6% sales tax.

1FLYR-N

FDANEWS



Unique Device Identifier (UDI) Rule Implementation and Compliance Guide

The rush to compliance is in full swing. By Sept. 24, 2015, all implantable, life-saving or life-supporting devices must comply with the new UDI requirements. By 2018 all devicemakers must be in compliance.

You'll need to understand what UDI is … who it applies to … what the exceptions to the rule are … what deadlines you must meet … what UDI issuing agencies are ... and how to work with them. Thankfully, help is here.

With **Unique Device Identifier (UDI) Rule Implementation and Compliance Guide**, you'll gain a clear understanding of this complex new rule and learn to work with it more successfully. You will learn:

- The timetable for implementation;
- Which devices must comply with the rule and which do not;
- What information must be included on product labels;
- How to submit device identification information to the GUDID;
- About the accredited UDI issuing agencies and their roles;
- And more!

Unique Device Identifier (UDI) Rule Implementation and Compliance Guide is fully updated to reflect the final rule, chapter by chapter the report includes the critical information you need to get down to the real nitty gritty of complying with the UDI rule.

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/50126
3. **FAX:** +1 (703) 538-7676
4. **MAIL:** FDAnews 300 N. Washington St., Suite 200 Falls Church, VA 22046-3431

☑**Yes!** Please send me ____ copy(ies) of ***Unique Device Indentifier (UDI) Rule Implementation and Compliance Guide*** at the price of $397 each for PDF format.

Name _____

Title _____

Company _____

Address _____

City_____ State _____ Zip code _____

Country _____

Telephone _____

Fax _____

Email _____

METHOD OF PAYMENT

❑ Check enclosed (payable to FDAnews)

❑ Bill me/my company. Our P.O.# _____

❑ Charge my credit card:
❑ Visa ❑ MasterCard ❑ American Express

Credit card no. _____

Expiration date _____

Signature _____
(Signature required on credit card and bill-me orders)

15FLYR-N