Smith & Nephew, Inc. 4/30/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District Office
One Montvale Avenue, 4th floor
Stoneham, MA 02180
Phone 781.587.7500
Fax 781.587.7556

WARNING LETTER
CMS # 457814

UNITED PARCEL SERVICE
OVERNIGHT DELIVERY

April 30, 2015

Michael G. Frazette. President
Advanced Surgical Devices
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810

Dear Mr. Frazette:

The Food and Drug Administration (FDA) conducted an inspection of your firm's medical device operations at Smith & Nephew Inc., 150 Minuteman Road, Andover, MA, from March 4 through 26, 2015. During the inspection, an investigator from the United States FDA determined that your firm is a specification developer for arthroscopy and gynecology devices, including the TRUCLEAR ULTRA Reciprocating Morcellators 4.0. Under section 201(h) of the Federal Food, Drug, and

Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

We received your response dated April 16, 2015 from Gerard D. Porreca, Senior Vice President, Quality and Regulatory Affairs, which responded to the Form FDA 483, List of Inspectional Observations issued to your firm on March 26, 2015. Our comments regarding the adequacy of your response are described below.

Your significant violations are as follows:

1. Failure to establish and maintain procedures for verifying or validating corrective and preventive actions (CAPA) to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, during the inspection eight corrective action reports were reviewed and did not contain sufficient information to ensure corrective actions were completed and verified as effective. For example:

- CAR 12-0014 was opened on September 12, 2012 to address complaints of loss of visualization with your TRUCLEAR ULTRA Reciprocating Morcellators. The CAPA investigation confirmed that a component was out of specification, specifically, undersized sluff chambers. Your firm instituted a product hold on August 29, 2012 and reworked existing inventory to replace the undersized sluff chambers. Corrective actions included increased sampling of sluff chambers used in production until the dimensions of the sluff chambers were revised in October 2013. A Health Hazard Assessment (HHA) for these products was finalized on January 20, 2013 and the CAR was closed on July 29, 2013.
    - The closed CAR did not include verification of effectiveness and your firm continues to receive complaints regarding the loss of visualization and undersized sluff chambers for your TRUCLEAR ULTRA Reciprocating Morcellators 4.0.
    - Your firm released **(b)(4)** reworked lots from product hold in September and October 2012. These products were distributed prior to finalizing the HHA on January 20, 2013, which is contrary to your own procedure, Product Hold/Suspension Doc # 1400105, which indicates that evaluations, including HHA's, should be complete before removing a product hold.

- CAPA MMP 13-0003 was opened on September 17, 2013 to address incorrect translation of the term, “non-absorbable suture” in the IFU for TwinFix Ultra Preloaded Suture Anchors. The correct term was “absorbable suture”. The CAPA noted that additional translation errors were identified with other device IFU’s on or around March 2014. At the time of the inspection on March 4, 2015, this CAPA was still open and there was no documentation that all of the translation errors had been corrected.
- CAPA MMP 13-0004 was opened on December 2, 2013 to address an increased complaint rate for Beaver Blade device breakage in the field. The CAPA identified three specific tasks that were due on or before March 2014, that would mitigate the issue. At the time of the inspection on March 4, 2015, this CAPA was still open and there was no documentation that the required tasks were completed or deemed to be effective.
- CAR A13-0006 was opened on April 10, 2013 to address a large number of complaint investigations that had been open for greater than 90 days. The CAPA identified numerous action items with specified target due dates. At the time of the inspection on March 4, 2015, this CAPA was still open and there was no documentation that all action items had been completed or deemed to be effective.

We understand from your response dated April 16, 2015, that you have placed a hold on TRUCLEAR Ultra Reciprocating Morcellators 4.0 shipments, while you further investigate the issues identified with this device. We also understand that you are completing another Health Risk Assessment (HRA) concerning complaints associated with CAR 12-0014, which is due to be completed by May 29, 2015. Please inform us of the results as soon as these evaluations are complete.

Your response is not adequate since you did not provide complete documentation of your corrections. We understand that you are implementing systemic improvements to your CAPA system and hope to verify effectiveness of the revisions by January 2016. In response to this Warning Letter, you should provide us with an update of these activities, including confirmation of a separate Quality Manager to oversee this revised system.

2. Failure to establish procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, on August 28, 2012, your firm confirmed that TRUCLEAR Ultra Morcellators had not undergone any validation studies to confirm that **(b)(4)** ethylene oxide (EtO) sterilization cycles did not adversely affect the devices. However, your firm released **(b)(4)** lots of reworked Reciprocating Morcellators under NCMR 11-0189 and NCMR 11-0190 without evaluating the effects of **(b)(4)** EtO sterilization cycles on these reworked devices.

Your response is not adequate since you did not provide complete documentation of your corrections. We understand that you are conducting a retrospective review of your non-conforming material reports for reworked products. In response to the Warning Letter, you should provide us with a summary of this review when complete, including a description of any corrective actions that need to be taken.

3. Failure to establish and maintain procedures to verify device design to ensure that the design outputs meets the design input requirements, as required by 21 CFR 820.30(f). For example, design verification of the TRUCLEAR Ultra Reciprocating Morcellators was conducted in July 2012 after changes were made to the device, including a change to the material of the outer tube. The final test report was approved on July 27, 2012 even though results confirmed **(b)(4)** out of **(b)(4)** failures of the **(b)(4)** test during the **(b)(4)** Procedure for Hysteroscopic blades. Your response indicated that this particular verification was considered to be a "line-extension of an existing product" and was not subject to your design control procedure, Design Controls Procedure Doc # 1420006, Rev. N.

Your response is not adequate since you did not provide complete documentation of your corrections. We understand that you will be conducting a retrospective design review of all currently marketed "line extension" products to ensure design outputs have been properly verified. We also note that you have placed a hold on the TRUCLEAR ULTRA Reciprocating Morcellator 4.0 in response to FDA-483 observation #1. In response to this Warning Letter, please provide us with a summary of your design review when completed, including a description of any corrective actions that need to be taken.

4. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. We observed that **(b)(4)** scheduled internal audits (including audits of CAPA and design controls) were not conducted in Q3 and Q4 of 2014 as required by your procedure, Quality Assurance Internal Audit Program Doc # 1420018. Justification for the failure to conduct these audits was not documented until March 5, 2015. We also confirmed that **(b)(4)** internal audits (**(b)(4)** in Q4 2013 and **(b)(4)** in Q2 2014) were conducted by individuals whose normal scope of responsibility included the areas audited. This is contrary to your own procedures.

We understand that you have hired **(b)(4)** employee to assist with your audit functions and will be re-auditing at least **(b)(4)** areas within Smith & Nephew, Andover, MA. We also understand that an outside expert will assess the effectiveness of these audits. These corrective actions appear adequate to address the violation. In response to this Warning Letter, please inform us of when these actions have been completed.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Please send your reply to the Food and Drug Administration, Attention: Karen N. Archdeacon, One Montvale Avenue, Stoneham, MA 02180. If you have questions regarding any issues in this letter, please contact Ms. Archdeacon at 781-587-7491.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Joseph Matrisciano
Acting District Director
New England District Office

Cc:

Oliver Bohuon, CEO
Smith & Nephew, plc
15 Adam Street
London WC2N 6LA
United Kingdom

More in Compliance Actions and Activities

Warning Letters

2015

2014

2013

2012

2011

2010

2009

2008

2007

2006

2005

Tobacco Retailer Warning Letters

Page Last Updated: 05/04/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA