Inspections, Compliance, Enforcement, and Criminal Investigations

AngioDynamics, Inc. 5/27/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New York District
158-15 Liberty Ave.
Jamaica, NY 11433

May 27, 2011

WARNING LETTER NYK-2011-23

VIA UNITED PARCEL SERVICE

Mr. Johannes C. Keltjens
CEO/President
AngioDynamics, Inc.
14 Plaza Drive
Latham, New York 12110

Dear Mr. Keltjens:

During an inspection of your firm located in Queensbury, New York, on January 4 - 13, 2011, an investigator from the United States Food and Drug Administration (FDA) determined your firm manufactures hemodialysis catheters, angiographic catheters, guide-wires and accessories, image guided vascular access products, endovascular laser venous system products, and oncology products. 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 ar intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

We received responses from S. Michael Sharp, Ph.D., V.P. of Regulatory Affairs, dated January 26 and 27, 2011, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, issued to you. We address these responses below, in relation to each of the noted violations. Your firm's response dated March 1, 2011, was not reviewed because i was not received within 15 business days of issuance of the FDA 483. This response may be evaluated along with any other written material you provide in response to the violations cited in this Warning Letter.

Our inspection revealed your Centros Chronic Hemodialysis Catheter Set is misbranded under section 502(t)(2) of the Act, 21 U.S.C 352 (t)(2), in that your firm failed or refused to furnish material or information respecting the devices required under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR) regulation. These violations include, but are not limited to, the following:

1. Failure to include all information reasonably known to your firm in your medical device report, as described in 21 CFR 803.50(b), as required by 21 CFR 803.52.

For example, your report, MDR #1319211-2010-00020 did not contain information known to you in Complaint #100063 involving an IRE Single Electrode Probe. Your complaint file indicates you were aware that the **(b)(6)** yet this information was not included in the initial MDR you submitted to FDA.

2. Failure to report to FDA no later than 30 calendar days after the day that your firm received or otherwise become aware o

information, from any source that reasonably suggests a device that you market may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a)(1).

For example, you became aware of the event in Complaint #100055 on February 25, 2010, involving the IRE System, but the MDR report was not submitted until March 31, 2010. We are unable to determine the adequacy of your responses because you did not provide a copy of the revised MDR procedures.

Our inspection also revealed your Centros Chronic Hemodialysis Catheter devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. 360i, and 21 CFR Part 806 - Reports of Corrections and Removals regulation. Significant violations include, but are not limited to, the following:

Failure to submit a written report to FDA of any correction or removal of a device to reduce a risk to health posed by the device, as required by 21 CFR 806.10(a)(1).

For example, you failed to report a field correction as a result of three complaints associated with tunneling device breakage with respect to the Centros Chronic Hemodialysis Catheter device.

We are unable to determine the adequacy of your responses because you did not provide a copy of the revised recall procedures.

You 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 Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within 15 business days from the date you receive this letter of the specific steps you have taken to correct the noted violations, as well as an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions you have taken. If your planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of these activities. If corrections and/or corrective actions cannot be completed within 15 business days, state the reason for the delay and the time within which these activities will be completed. Your response should be comprehensive and address all violations included in this Warning Letter.

In addition, FDA has noted nonconformances with regards to section 501(h) of the Act (21 U.S.C. 351(h)), which are deficiencies of the following Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at 21 CFR Part 820. These nonconformities include, but are not limited to, the following:

Failure to adequately review and evaluate all complaints to determine whether an investigation is necessary, as required by 21 CFR 820.198(b).

For example, you maintain two complaint systems, the Complaint Log for complaints related to disposable devices and the Service Order Log for complaints related to hardware serviced by the firm. The complaints in the Service Order Log related to the Precision Laser 980, Precision Laser 980+, IRE Generator and Pulse Spray Injectors, are not adequately reviewed and evaluated. The 2010 Service Order Log contains 213 of 360 total service orders classified as complaints. However, there is no evidence within the Service Order Log or the complaint files that shows the two departments communicate with each other in regard to complaint evaluation and review.

We reviewed your responses and conclude that they are not adequate because they do not provide evidence to show that all complaints are being captured, reviewed, and appropriately handled.

Your response should be sent to:

Lillian C. Aveta
Compliance Officer
New York District Office, Compliance Branch
Food and Drug Administration
158-15 Liberty Ave.
Jamaica, NY 11433

If you have any questions about the content of this letter please contact Ms. Aveta at 718-662-5576.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your

responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,
/S/
Ronald M. Pace
District Director
New York District

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