Inspections, Compliance, Enforcement, and Criminal Investigations

Medtronic Navigation, Inc 5/7/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3551

May 7, 2010

WARNING LETTER

UPS
RETURN RECEIPT REQUESTED

Mr. William A. Hawkins
President
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, Minnesota 55432

Ref# DEN-10-10 WL

Dear Mr. Hawkins:

During an inspection of your firm Medtronic Navigation, Inc., located at 826 Coal Creek Circle, Louisville, Colorado, on January 2 - February 4, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures Class II image guided surgical systems for spinal, cranial, and Ear, Nose, and Throat (ENT) applications, including their sterile and non-sterile accessories. 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 are intended to affect the structure or function of the body. Significant deviations include, but are not limited to, the following:

1. You failed to establish and maintain procedures for implementing corrective and preventive action, including investigating the cause of nonconformities relating to product, processes and the quality system, as required by 21 CFR 820.100(a)(2) and your SOP-C-1010 Rev 4.

Specifically, in 2009 you had **(b)(4)** software defects noted in your **(b)(4)** system that were noted as being "Open, not assigned" without disposition and did not have "Severity", "User Impact" and "Probability of Harm" fields completed as required by your SOP.

2. Failure to establish and maintain procedures for validating the device design, including risk analysis, 21 CFR 820.30(g). Specifically, your risk analysis report for the Treon StealthStation titled **(b)(4)** "StealthStation Hazard Analysis Report, dated **(b)(4)** noted that the report failed to establish or define what an acceptable risk level is.

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, that includes a requirement that all complaints are
evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 830, Medical Device Reporting, 21 820.198 (a)(3). Specifically, your complaint **(b)(4)** stated that during surgery, the physician drilled a bur hole and noticed it wasn't over the tumor. When the accuracy was checked, it was determined that the image was off by 1.5 cm. The complaint file stated **(b)(4)** This complaint was not submitted as an MDR reportable event. The precious inspection noted a siimilar deviation.

In addition, of **(b)(4)** cases reviewed in the customer tracking system, two which pertained to device failures were not considered as complaints.

4. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d) and your SOP H-12 "Final System Inspection". Specifically, StealthStation **(b)(4)** did not have all required activities completed prior to release.

We acknowledge receipt of your FDA 483 responses dated February 19, March 10, March 15, March 19, March 26 and April 23, 2010. You appear to be addressing our concerns. Your responses will be included in your pem1anent file.

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 Waming Letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, premarket approval applications for devices to which the Quality System regulation deviations 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 (15) working days from the date you receive this letter of any additional steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violation(s), or similar violation(s), from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is 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, issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance 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.

Your response should be sent to: Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087, Attention: William H. Sherer, Compliance Officer. If you have any questions, please contact Mr. Sherer at (303) 236-3051.

Sincerely,

/S/
H. Thomas Warwick
Denver District Director

Cc: Mr. James L. Cloar III
Vice President and General Manager
Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, CO 80027

Links on this page: