SureTek Medical 3/3/16

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309
Telephone: 404-253-1161
FAX: 404-253-1202

March 3, 2016

VIA UPS

Mike Sammon
President and Chief Executive Officer
SureTek Medical
25-B Maple Creek Circle
Greenville, SC 29607-4800

WARNING LETTER
(16-ATL-07)

Dear Mr. Sammon:

During an inspection of SureTek Medical, 25-B Maple Creek Circle, Greenville, South Carolina, on October 26 – November 10, 2016, an investigator from the U.S. Food and Drug Administration (FDA) determined that your firm manufactures various medical devices such as orthopedic and laparoscopic instruments. These products are devices within the meaning of Section 201(h) of the Federal Food, Drug, and

Cosmetic Act (the Act) [21 United States Code (U.S.C.) § 321(h)] in that 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.

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 (CGMP) requirements of the Quality System (QS) regulations found at Title 21 of the Code of Federal Regulations Part 820 (21CFR Part 820).

A FORM FDA 483, Inspectional Observations, was issued to you at the end of our inspection (copy enclosed). We have received your responses dated December 02, 2015; December 23, 2015; and February 08, 2016, concerning our investigator's observations identified on the FDA 483. We address these responses below, in relation to each of the noted violations. The violations documented on the FDA 483 issued include, but are not limited to, the following:

1. Procedures for monitoring and control of process parameters for a validated process have not been established as required by 21 CFR 820.75(b). During our inspection of your facility, the following violations were observed:

    a. Your firm's validated cleaning process is not routinely monitored to assess contamination levels for reprocessed single-use devices subjected to the process. The most recent assessments for contamination were performed in 2012 as part of Cleaning Validation of Compressed Sleeves, Protocol #12019 (for hemoglobin and bioburden) and Cleaning Validation of Orthopedic, ENT and Laparoscopic Instruments, Protocol #12020-A (for hemoglobin and protein). However, your firm's procedure, titled QAP008-Appendix C, Validation of Product, Equipment and Process for EO Sterilization, Rev. 1, states, "Product bioburden is controlled through the cleaning process and monitored on a quarterly basis...;" . No documented evidence was provided during the current inspection to support this requirement as required by your procedures.

Our office has reviewed your firm's response letters dated December 02, 2015; December 23, 2015; and February 08, 2016 concerning this observation. In your response letter dated February 08, 2016, you indicated that bioburden test samples for Q1 2016 are scheduled for testing at **(b)(4)** in March 2016. We request that your firm submit a copy of the testing results to our office for review.

Your December 23, 2015 response letter indicated that your firm would be validating the **(b)(4)** for monitoring your firm's cleaning process. In your February 08, 2016 response letter, you indicated that your firm had implemented the **(b)(4)** for monitoring your firm's cleaning process. We request that your firm provide a copy of the validation of the **(b)(4)** for our review.

b. Your firm has failed to adequately identify the worst-case product used during the validation of your firm's sterilization process. The 2014 and 2013 Performance Qualification of Sterilization Process reports both state under item #2 that "the **(b)(4)** devices within the load would present a bioburden challenge". During our review of sterilization records, Sterilization Batch Record (SBR) #782 indicated that **(b)(4)** devices were sterilized in that load, with over **(b)(4)** more devices than used in the validations.

Your response letters dated December 02, 2015; December 23, 2015; and February 08, 2016, did not adequately address this violation. Specifically, your December 02, 2015 response letter indicates that the annual sterilization validation for the **(b)(4)** (PQ009-2015, SBR # 798) concluded that the configuration of the worst-case load can be sterilized to a sterility assurance level $>10^{-6}$. We request that your firm provide our office a copy of the sterilization validation, PQ009-2015, SBR # 798, for our review.

c. The numbers of samples chosen for use in the Cleaning Validation studies were not based on a valid statistical technique.

Your response letters fail to adequately address the validity of the statistical techniques used for selecting the number of samples for testing during the cleaning validation studies performed by your firm.

We acknowledge the corrective actions your firm has implemented in regard to the FDA 483 observations that are not discussed in this letter. Those corrective actions appear to adequately address the observations identified on the FDA 483, but will require verification during our next inspection at your facility.

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 our 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 (including any systemic corrective actions) 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.

Your firm's response should be sent to: Derek Price, Compliance Officer, Atlanta District Office, 60 Eighth Street NE, Atlanta, Georgia, 30309. If you have any questions about the contents of this letter, please contact: Compliance Officer Price by phone at (404) 253-2277 or by fax at (404) 253-1201.

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/
Ingrid A. Zambrana
District Director
Atlanta District Office

More in 2016

- FDA Archive
- Combination Products
- Advisory Committees
- Regulatory Information
- Safety
- Emergency Preparedness
- International Programs
- News & Events
- Training & Continuing Education
- Inspections & Compliance
- Federal, State & Local Officials
- Consumers
- Health Professionals
- Science & Research
- Industry