**U.S. Food and Drug Administration**
Protecting and Promoting *Your* Health

# MicroAire Surgical Instruments, LLC 12/29/14



**Department of Health and Human Services**

Public Health Service
Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5455

FAX: (410) 779-5707

**WARNING LETTER**
**CMS# 440739**

December 29, 2014

**Via UPS**

Mr. George M. Saiz, President
MicroAire Surgical Instruments, LLC
3590 Grand Forks Blvd
Charlottesville, VA 22911-9001

Dear Mr. Saiz:

During an inspection of your firm located in Charlottesville, Virginia on August 11, 2014 through August 22, 2014, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Endotine and Ultratine biodegradable implants. 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 the Endotine and Ultratine biodegradable implants 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 several responses from your firm concerning our investigators observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to your firm. We address the responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Procedures to ensure that where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures were not established, as required by 21 CFR 820.75(a). Specifically, your firm failed to provide a rationale for grouping together the Ultratine and Endotine device lines in the same device family for the validation of the **(b)(4)** sterilization process.

We have reviewed your firm's response and conclude that it is not adequate. Your firm provided DCO 14967, including a comparison table of characteristics to demonstrate adherence to its **(b)(4)** procedure. However, your firm failed to provide documentation of an evaluation of the Ultratine and Endotine product families for the differences in functional characteristics noted in the observation. Your firm also failed to provide adequate documentation of corrective action. Specifically, your firm failed to provide a retrospective review of the determinations of other product families to ensure relevant functional characteristics are incorporated in the evaluations. In addition, no documentation of independent sterilization validations of the Endotine and Ultratine products was provided.

2. Software used as part of production and the quality system has not been validated for its intended use according to an established protocol, as required by 21 CFR 820.70(i). Specifically, software validation was not conducted for the following pieces of equipment:

| Automated Production Equipment | Quality Inspection Equipment |
|---|---|
| **(b)(4)** | **(b)(4)** |
| **(b)(4)** | **(b)(4)** |
| **(b)(4)** | |

The corrective actions outlined in your firm's responses appear adequate and will be verified during a during a follow-up FDA inspection.

Our inspection also revealed that your devices are misbranded under Section 502(t)(2) of the Act 21 USC 352 (t)(2), in that your firm failed or refused to furnish material or information respecting the devices that is required by or under Section 519 of the Act, 21 USC 360i, and 21 CFR Part 803 – Medical Device Reporting (MDR) Regulation. Significant deviations include, but are not limited to:

3. Your firm failed to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17(a). For example, after reviewing your firm's MDR Procedure titled "Complaint Handling, MAP RQ-009, Rev. AB," dated September 4, 2013, the following issues were noted:

a. MAP RQ-009, Rev. AB, does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as required by 21 CFR 803.17(a)(1). For example:

i. The procedure omits the definitions from 21 CFR 803.3 for the terms "MDR reportable event", "become aware" and "caused or contributed." The exclusion of the definitions for these terms from the procedure may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).

b. MAP RQ-009, Rev. AB, does not establish internal systems that provide for timely transmission of complete medical device reports, as required by 21 CFR 803.17(a)(3). Specifically, the following are not addressed:

i. The procedure does not include or refer to instructions for how to obtain the FDA 3500A form.

ii. While the procedure includes instructions for filing a supplemental report, it does not reference the timeframe for the submission of such reports.

Your firm's response is not adequate. Your firm submitted a revised MDR procedure. After reviewing your firm's revised MDR procedure titled "Complaint Handling, MAP RQ-009, Rev. AC," dated September 4, 2014, the following issues were noted:

a. MAP RQ-009, Rev. AC, does not establish internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, as required by 21 CFR 803.17(a)(1). For example:

i. The procedure omits the definitions from 21 CFR 803.3 for the terms "MDR reportable event", "become aware" and "caused or contributed." The exclusion of the definitions for these terms from the procedure may lead your firm to make an incorrect reportability decision when evaluating a complaint that may meet the criteria for reporting under 21 CFR 803.50(a).

b. MAP RQ-009, Rev. AC, does not establish internal systems that provide for timely transmission of complete medical device reports, as required by 21 CFR 803.17(a)(3). Specifically, the following are not addressed:

i. The procedure does not include or refer to instructions for how to obtain the FDA 3500A form.

ii. While the procedure includes instructions for filing a supplemental report, it does not reference the timeframe for the submission of such reports.

The eMDR Final Rule requiring manufacturers and importers to submit electronic Medical Device Reports (eMDRs) to FDA was published on February 13, 2014. The requirements of this final rule will take effect on August 14, 2015. If your firm is not currently submitting reports electronically, we encourage you to visit the following web link for additional information about the electronic reporting requirements:

**http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm (http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm)**

If your firm wishes to discuss MDR reportability criteria or to schedule further communications, it may contact the MDR Policy Branch at **ReportabilityReviewTeam@fda.hhs.gov (mailto:ReportabilityReviewTeam@fda.hhs.gov)**.

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.

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 (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:

Ernest Bizjak
U. S. Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, Maryland 21215

Refer to CMS case # 440739 when replying. If you have any questions about the contents of this letter, please contact: Ernest Bizjak at (410) 779-5715 or via email at ernest.bizjak@fda.hhs.gov.

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 yours,
/S/
Evelyn Bonnin
District Director
Baltimore District Office

CC:
Mr. Louhon Tucker, President and CEO
Colson Associates, Inc.
One North Franklin Street, Suite 2420
Chicago, IL 60606-3452

**2006 (/ICECI/EnforcementActions/WarningLetters/2006/default.htm)**

**2005 (/ICECI/EnforcementActions/WarningLetters/2005/default.htm)**

**Tobacco Retailer Warning Letters (/ICECI/EnforcementActions/WarningLetters/Tobacco/default.htm)**