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

DIMA S.L. 10/15/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
White Oak Building 66
Silver Spring, MD 20993

OCT 15, 2014

WARNING LETTER

VIA UNITED PARCEL SERVICE

Francisco Farrer
General Manager
Desarrollo e Investigación Médica Aragonesa (DIMA) S.L.
Poloigono Industrial Mediavega Parcela 2.9
Calatayud, Zaragoza 50300
Spain

Dear Mr. Farrer:

During an inspection of your firm located in Calatayud, Zaragoza, Spain on June 30, 2014, through July 3, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures Anchorsure, Remeex slings, needleless slings, and incontinence mesh. 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 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. These violations include, but are not limited to, the following:

1. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a).

For example, in 2011, the manufacturer of your firm's Computer Numeric Controlled (CNC) machine LAR 179 installed the machine, its software programs, and produced and tested sample parts. None of the activities related to installation and operational qualification of LAR 179 were documented.

2. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure, as required by 21 CFR 820.70(b). For example:

a. Your firm does not have procedures for handling changes to a specification, method, process or procedure.

b. Your firm installed a new part on its weaving machine to address a high number of rejections. However, your firm does not have documentation supporting that this change was verified or validated according to 21 CFR 820.75 prior to implementation.

3. Failure to establish and maintain procedures to control environmental conditions that could reasonably be expected to have an adverse effect on product quality and failure to periodically inspect environmental control systems to verify that the system is adequate and functioning properly, as required by 21 CFR 820.70(c). For example:

a. Your firm does not have environmental control procedures.

b. Your firm has not established control over environmental conditions that could reasonably be expected to have an adverse effect on product quality. Specifically, the ventilation system for clean rooms **(b)(4)** and **(b)(4)** are shut down overnight and a **(b)(4)** minute waiting period has been implemented after start up each morning. However, your firm has not validated the clean rooms are operating within specifications after a **(b)(4)** minute waiting period.

4. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i) For example:

a. Your firm has no design change procedure.

b. Your firm did not consider updating your firm's risk analysis for a design change implemented to include an insertion tip in the Contasure Needleless Mess Kit.

Failure to establish and maintain design validation procedures to ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions, as required by 21 CFR 820.30(g). For example:

a. Your firm's Procedure **(b)(4)**, Design and Development, does not include:

i. Requirements for identifying acceptance criteria for design validation activities.

ii. Requirements for conducting risk analysis.

b. Your firm conducted design validation activities for two projects: **(b)(4)**, and the **(b)(4)**. There were no documented acceptance criteria for either of your firm's design validation activities that show your devices
conform to the defined user needs and intended uses.

5. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example:

a. Your firm's corrective and preventive action procedure does not identify the actions needed to correct and prevent recurrence of nonconforming products and other quality problems.

b. Your firm has not implemented and recorded corrective actions needed to correct and prevent identified quality problems for the following:

i. CAPA 2012-01-23 identified re-training as a corrective action. However, this corrective action was not documented.

ii. CAPA 2012-02-08 was opened after receiving a complaint that the monofilament used for the Surelift Anchor broke during surgery. Your firm determined that corrective actions were not needed. However, the justification for no action needed was not documented.

6. Failure to establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product, as required by 21 CFR 820.90(b)(1).

For example, your firm's nonconforming proceduredoes not require documentation of disposition of nonconforming products.

Given the serious nature of the violations of the Act, Anchorsure, Remeex slings, needleless slings, and incontinence meshmanufactured by your firm are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you regarding the adequacy of your firm's responses and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Also, U.S. 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 deviations are reasonably related will not be approved until the violations 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, including 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. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 2622, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case # 439076 when replying. If you have any questions about the contents of this letter, please contact: Daniel Walter, Chief, Foreign Enforcement Branch, at telephone (301) 796-5587or by fax (301) 847-8139.

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/
Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health