



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Southwest Region 94918d

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

July 14, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bradley J. Stringer
Manager and CEO
Inceptio Medical Technologies, L.C.
532 N. Kays Drive
Kaysville, UT 84037

Ref # DEN-04-11

Dear Mr. Stringer:

During the period April 28 through May 7, 2004, an investigator from the Salt Lake City, Utah office of the U.S. Food and Drug Administration (FDA) conducted an inspection of your establishment. Our investigator determined that your firm manufactures ultrasonic vascular imaging systems and sterile accessories for the imaging system. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. § 321(h)].

As discussed with you at the close of the inspection, and described in the Form FDA-483 left with you, the investigator found evidence that your medical devices are adulterated under Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with Current Good Manufacturing Practice (CGMP) requirements. CGMP requirements are set forth in FDA's Quality System (QS) regulation, Title 21, Code of Federal Regulations, Part 820 (21 CFR 820). Significant deviations include, but are not limited to, the following:

1. Failure to validate a process for which results cannot be fully verified by subsequent inspection or test, [21 CFR 820.75(a)]. Your sterilization process validation for the Punctsure Vascular Access Imaging Procedure Kits is inadequate in that it was performed on product manufactured for you by another firm. You now manufacture these device accessory kits ~~X X X X X X X X~~. There is no documentation to support the contention that the bioburden, packaging integrity and sealing parameters of your

currently manufactured product is the same as that upon which the validation was conducted. In addition, the assembly and test processes in your Punctsure II Electronic Assembly & Test Procedure have not been validated.

We acknowledge receipt of your July 8, 2004 correspondence which addresses this item. Your corrective action will be fully evaluated during our next inspection of your firm.

2. Failure to establish and maintain procedures to ensure that Device History Records (DHR) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR), [21 CFR 820.184]. You do not have a written procedure for establishing and maintaining Device History Records.

Our investigator reviewed ~~X~~ DHRs, which covered the manufacture of ~~x x~~ Punctsure Vascular Access Imaging Procedure Kits. The review disclosed that the DHRs did not include the dates of manufacture, the quantity manufactured, the quantity released for distribution, acceptance records, and the primary identification label and labeling used on the product, as required.

3. Failure to establish and maintain procedures for the identification, documentation, validation, review, and approval of design changes before their implementation, [21 CFR 820.30(i)]. Design changes made to your Punctsure Ultrasonic Vascular Imaging System and its software in ~~x x x~~ were not validated, and approval of the design changes were not documented.
4. Failure to review and evaluate all complaints to determine whether an investigation is necessary, and when no investigation is made, maintain a record that includes the reason and name of the individual responsible for the decision not to investigate, [21 CFR 820.198 (b)]. ~~x~~ complaints were reviewed by our investigator. Although no investigation was conducted for any of these complaints, there was no record indicating the reason not to investigate or the name of the individual responsible for the decision.
5. Failure to establish and maintain procedures to control documents as required by your Document Control Policy, your Engineering Change Policy, and [21 CFR 820.40]. Our investigator observed that three versions of the Product Service Form had been used in taking product complaints; however, none of them matched the “master document” located on your firm’s computer network.
6. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, [21 CFR 820.50]. You do not have a procedure that clearly describes or references the specified requirements for purchasing and accepting biological indicators used in determining acceptability of the ~~x x x~~ sterilization of Punctsure Vascular Access Imaging Procedure Kits.

7. Failure to establish procedures for rework of nonconforming product to ensure that the product meets its approved specifications, [21 CFR 820.90(b)(2)]. Although you rework nonconforming product, you do not have a written procedure covering this operation.

We acknowledge receipt of your letter dated May 20, 2004, which responded to our form FDA-483. Your response is inadequate in that it does not contain specific steps you have taken or plan to take to address the conditions noted. It only contains a timeline for correcting the deviations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include seizure, injunction and/or civil penalties.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. 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.

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,



B. Belinda Collins
District Director