DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1431 Harbor Bay Parkway<br>Alameda, CA 94502-7070<br>(510) 337-6700 Fax:(510) 337-6702<br>Industry Information: www.fda.gov/oc/industry | 03/01/2010 - 04/05/2010*<br>FEI NUMBER<br>2939320 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

**TO:** Thomas E. Sgarlato, DPM, President and Chief Executive Officer

| FIRM NAME | STREET ADDRESS |
|---|---|
| Sgarlato Med, LLC | 1975 Hamilton Ave Ste 38 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| San Jose, CA 95125-5630 | Medical Device Manufacturer |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

*The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.*

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

A violation of the FD&C Act involving a device which might present a risk to health was not reported to FDA.

Specifically, your firm conducted a field correction of removing products, Sgarlato Labs GAIT Implant, 30-100-03 Large, from customers due to the product being incorrectly labeled. The products were labeled with two different lot numbers and incorrectly calculated expiration dates. According to three (3) customer complaints received from 2/13/2009 to 3/16/2009, the products outer packaging showed the Lot Number of "051700" with an expiration date of "2013/05" and an inner pouch label with Lot Number "091103a" with an expiration date of "2007/08". Your procedures for Lot Numbering, "LOT NUMBERING SYSTEM", "Document #: (b) (4) Effective Date: 2/25/02", "The lot number assigned to a "batch" or lot of final product will (b) (4) ", and the expiration dating is (b) (4) . According to you, the products (Sgarlato Labs GAIT Implant, 30-100-03 Large) were removed from the customer possession to reduce the potential risk that customers might use the products beyond their actual expiration dating. The field action was not properly reported to the US Food and Drug Administration.

## OBSERVATION 2

Procedures were not followed for the identification, documentation, validation or verification, review, and approval of design changes before their implementation.

Specifically, during my review of design controls specific to design changes, it was revealed that you modified/re-designed the (b) (4) Implant/"New Altered Hammer toe Implant" between "June 08" and "2/2/09". A review of the "DESIGN PLAN" and documentation located in the Design History File does not show that all deliverables or supporting documentation for design inputs, design reviews, design output, and design validation/verification were established or reviewed prior to releasing/transferring the design to manufacturing. For example the design plan states for Design Inputs -

- "(b) (4) " and "(b) (4) " and dated "6/08". It is unclear what inputs were provided on or about "6/08";
- "(b) (4) " was marked as "Yes". No documentation was present in the

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| | Mark E Chan, Investigator | 04/05/2010 |

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DHF to support (b) (4);
- "(b) (4)" was marked as "Yes". The list was not present in the DHF.

Design Review Meeting -
- Left blank

Design Output -
- Only shows that "(b) (4)", "(b) (4)", and "(b) (4)" were completed on either "6/08" or "2/2/09" all other design elements were left blank with no justification provided.

Design Verification -
- Left blank

Design Validation -
- Indicates "Date Completed" as "6/08". No supporting data was present in the DHF

**OBSERVATION 3**

Procedures for planning and conducting reviews of the design results at appropriate stages of the device's design development were not implemented.

Specifically, during my review of design controls specific to overall design controls and design changes, it was revealed that you modified/re-designed the (b) (4) Implant/"New Altered Hammer toe Implant" between "June 08" and "2/2/09", but no design documents/record were available to support that design reviews were conduct throughout the design process. According to your design control procedure, "DESIGN CONTROL, Document #: (b) (4), Effective Date: 10/25/05", under section "7.0 DESIGN REVIEWS", in subsection 7.1 states:

"(b) (4)

*7.1.1.* (b) (4)

*7.1.2.* (b) (4)

*7.1.3.* (b) (4) "

A review of the "DESIGN PLAN" and documents located in the Design History File do not show that design review meetings were held. No documentation or records were available to support that review meetings were conducted.

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**OBSERVATION 4**

Design input requirements were not fully documented.

Specifically, from my audit of your design control process and documentation, it was revealed from a review of your "DESIGN PLAN" titled "New Altered Hammertoe implant", not all design inputs were documented. According to your design control procedure, "DESIGN CONTROL, Document #: (b) (4) Effective Date: 10/25/05", under section "5.0 DESIGN INPUT", in subsection 5.3 states:

"*5.3.1.* (b) (4)
(b) (4)
*5.3.2.* (b) (4)
*5.3.3.* (b) (4)
(b) (4)

The "DESIGN PLAN" titled "New Altered Hammertoe implant", dated 6/2008 and design history file for the (b) (4) Implant does not contain supporting documentation for inputs related to functional or performance requirements.

**OBSERVATION 5**

Procedures for verifying that design output meets design input were not implemented.

Specifically, from my audit of your design control process and documentation, it was revealed from a review of your "DESIGN PLAN" titled "New Altered Hammertoe implant", documentation was not available to verify that design output met design inputs. According to your design control procedure, "DESIGN CONTROL, Document #: (b) (4), Effective Date: 10/25/05", under section "8.0 DESIGN VERIFICATION", states:

"*8.1* (b) (4)
(b) (4)
*8.2* (b) (4)
*8.2.1.* (b) (4)
*8.2.2.* (b) (4)
*8.2.3.* (b) (4)"

Documentation was not available to document that design outputs were verified to meet design input requirements. In addition, a review of the Design Hisotry File (DHF) for the (b) (4) Implant showed that (b) (4) different (b) (4) materials (b) (4) ) were utilized to determine which material would be use to manufacture the implants from. According to the DHF, it showed that (b) (4) of the materials were not acceptable (b) (4) (b) (4) ) due to not meeting specifications. A review of Device History Record for the (b) (4) Lot Number (b) (4) the (b) (4) material used was the (b) (4) . No documentation was avialble to justify the use of this material.

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## OBSERVATION 6

Procedures for acceptance activities were not complete and implemented.

Specifically, during my audit of production and process controls, it was revealed that incoming inspections are not being performed in accordance to your Standard Operating Procedures (SOP). According to you receiving inspection procedure, "RECEIVING INSPECTION, Document #: (b) (4), Effective Date: 08/29/06", under section "6.0 PROCEDURE FOR RECEIVING FABRICATED IMPLANTS", in subsection 6.6 states:

"(b) (4) ";

and under section "7.0 PROCEDURE FOR RECEIVING PACKGED IMPLANTS AND SIZERS", in subsection 7.8 states:

"(b) (4) ".

According to you, all incoming or received products are only (b) (4) inspected. For received implants you explained that you check the "Certification of Compliance" from the vendor (b) (4) and (b) (4) inspect all implants for (b) (4) There is no established procedure that outlines the actual receiving inspections that are performed.

In addition, a review of Device History Record (DHR) for the Sgarlato Med Gait Large Implant, 30-100-03, Lot Number 040109, with a "RECEIVING INSPECTION RECORD" dated "3/30/09", shows a "CERTIFICATE OF COMPLIANCE", "DATE SHIPPED 3/12/09" provided by your contract manufacturer (b) (4) that the (b) (4) /production formula used to manufacture the Gait Large Implants was "(b) (4) ". According to the "STANDARD MATERIAL CERTIFICATION" provided for the "(b) (4) ", "(b) (4) " the (b) (4) has an "Expiration Date" of "12/06/06". According to the Gait Large Implant DHR for Lot Number 040109 a quantity of (b) (4) implants were manufactured and packaged. A review of current inventory, as of 3/3/2010, it shows that (b) (4) implants remain in-house.

## OBSERVATION 7

Corrective and preventive action activities have not been documented, including the actions needed to correct or prevent recurrence of nonconforming product and other quality problems, the verification or validation of corrective actions, and implementation of corrective and preventive actions.

Specifically, your firm conducted a field correction of removing products, Sgarlato Labs GAIT Implant, 30-100-03 Large, from customers due to the product being incorrectly labeled. The products were labeled with two different lot numbers and incorrectly calculated expiration dates. According to three (3) customer complaints received from 2/13/2009 to 3/16/2009, the products outer packaging showed the Lot Number of "051700" with an expiration date of "2013/05" and an inner pouch

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label with Lot Number "091103a" with an expiration date of "2007/08". Your procedures for Lot Numbering, "LOT NUMBERING SYSTEM", "Document #: (b) (4), Effective Date: 2/25/02", "The lot number assigned to a "batch" or lot of final product will (b) (4) (b) (4)". According to you, the products (Sgarlato Labs GAIT Implant, 30-100-03 Large) were removed from the customer possession to reduce the potential risk that customers might use the products beyond their actual expiration dating. The corrective and preventive action activities were not documented. The Nonconformce Report, Report Number 11, dated "04Mar2009" associated with the "GAIT Implant Large, # 30-100-03", "Lot Number 051700" describes the nonconformance as "GAIT Implant Large Outer label imprinted with incorrect expiration date of 2013/05. The correct expiration date should be 2009/08". Under "DISPOSITION" it only explains "Removed From (b) (4) Inventory - "For Research Use Only." Under "CLOSE-OUT" it indicates that a corrective action is required, but not corrective action report was ever initiated to document the field action take to remove the product from the customers.

**OBSERVATION 8**

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements were not complete.

Specifically, during my audit of your production and process controls, it was revealed that your purchasing control procedures, "PURCHASING CONTROLS, Document #: (b) (4), Effective Date: 8/25/2006" and "PURCHASING, Document #: (b) (4), Effective Date: 5/19/2002" do not address step for qualifying supplier, contract manufacturers, or service providers. You maintain an "APPROVED SUPPLIER LIST, Document #: (b) (4), Effective Date: 1/16/03" which list your "Critical Suppliers" and "Non-Critical Supplier" but no procedures were available to address how these suppliers were evaluated or approved to meet specific requirements prior to utilizing their services.

**OBSERVATION 9**

The evaluation of potential suppliers, contractors, and consultants was not documented.

Specifically, during my audit of your purchasing control and supplier/contractor qualification, it was revealed that at least two "Critical Suppliers": the contract manufacturer of the implants, and the contract packaging firm, have not been audited by your firm and no documentation of evaluation/qualification were available to show that these supplier/contract manufacturers were qualified prior to utilizing their services. According to you, you have not performed any on-site audits of:

(b) (4)
(b) (4)

**OBSERVATION 10**

Products that do not conform to specifications are not adequately controlled.

Specifically, a review of Device History Record (DHR) for the Sgarlato Med Gait Large Implant, 30-100-03, Lot Number 040109, with a "RECEIVING INSPECTION RECORD" dated "3/30/09", shows a "CERTIFICATE OF COMPLIANCE",

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"DATE SHIPPED 3/12/09" provided by your contract manufacturer, (b) (4) that the (b) (4) /production formula used to manufacture the Gait Large Implants was "[redacted]". According to the "STANDARD MATERIAL CERTIFICATION" provided for the (b) (4) [redacted]", (b) (4) [redacted] " the (b) (4) [redacted] has an "Expiration Date" of "12/06/06".

No Nonconformance Report was generated and the lot was release to finished goods inventory on or about "5/8/09".

According to the Gait Large Implant DHR for Lot Number 040109 a quantity of (b) (4) implants were manufactured and packaged. A review of current inventory, as of 3/3/2010, showed that (b) (4) implants remain in-house

## OBSERVATION 11

Complaint handling procedures have not been implemented to ensure that all complaints are evaluated to determine whether the complaint should be filed as a Medical Device Report.

Specifically, during my audit of your corrective and preventive actions process specific to complaint handling and Medical Device Reporting (MDR), it was revealed that complaints are not being evaluated to determine MDR Reportability. A review of the three complaints received in calendar year 2009 (Complaint Numbers: 091802a, 090403a, and 091103) showed that no "MEDICAL COMPLAINT ANALYSIS RECORD" were filled out to evaluate/determine if the events were MDR reportable or evaluated for potential reportable device malfunctions. According you your complaint handling procedure, "Technical Calls and Customer Complaint Handling, Document #: (b) (4) Effective Date: 3/16/04" under section 5.0 "PROCEDURE", in subsection 5.5 is states:

"(b) (4) [redacted]".

No documentation was available to show that the complaints were evaluated to determine whether a malfunction occurred and if it were to recur whether it would be likely to cause a death or serious injury.

## OBSERVATION 12

Complaints involving the possible failure of labeling to meet any of its specifications were not investigated where necessary.

Specifically, during my audit of your corrective and preventive action process, specific to complaint handling, it was revealed that of the three complaimts received in calendar year 2009, no investigations were documented and no justification was documented to suppport not performing an investigation. All three complaints were associated with mis-labelling of the product (Sgarlato Med LLC Gait Implant Large, Product/Catalog Number 30-100-03) with the incorrect lot number ( Lot number 051700) on the outer packaging, incorrect expiration date (2013/05) on the outer packaging, and an expired lot number on the inner packaging. No investigations were documented or avialable to determine what the root cause of the event.

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## OBSERVATION 13

Quality audits were not conducted at sufficient regular intervals, as prescribed by internal procedures to verify that the quality system is effective in fulfilling your quality system objectives.

Specifically, during my audit of management controls, it was revealed that you have not conducted internal audits of your quality system. According to your internal quality audit procedure, "INTERNAL QUALITY AUDITS, Document #(b) (4), Effective Date: 5/19/02", it states under Section 4.0 that (b) (4)". According to you, internal quality audits of Sgarlato Med, LLC quality system has not been conducted, and no documentation were available.

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## Observation Annotations

Observation 1: (b) (4)
Observation 3:
Observation 5:
Observation 7:
Observation 9:
Observation 11:
Observation 13:

Observation 2: (b) (4)
Observation 4:
Observation 6:
Observation 8:
Observation 10:
Observation 12:

*** DATES OF INSPECTION:**
03/01/2010(Mon), 03/02/2010(Tue), 03/03/2010(Wed), 03/08/2010(Mon), 03/09/2010(Tue), 03/10/2010(Wed), 03/15/2010(Mon), 03/17/2010(Wed), 03/19/2010(Fri), 03/24/2010(Wed), 03/26/2010(Fri), 04/05/2010(Mon)

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