DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax:(410) 779-5707 Industry Information: www.fda.gov/oc/industry	06/10/2014 - 06/17/2014* FEI NUMBER 3001236105

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Khalil A. Jebraan, Vice President

FIRM NAME	STREET ADDRESS
Surgical Design Inc	7351 Lockport Pl Ste D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lorton, VA 22079-1571	Specification Developer

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

Procedures for design control have not been established.

Specifically, procedures to control design inputs, outputs, risk, verification, validation, review and transfer have not been established.

There is no design risk document for the [redacted]

Design review meetings were not performed for the [redacted]

Design verification results for the [redacted] including the identification of the design, methods, and the individuals performing the verification were not documented in the design history file.

OBSERVATION 2

Procedures for corrective and preventive action have not been adequately established.

Specifically, [redacted] initiated on 3/3/2014, for a customer stating that the hole on which the bell is inserted is smaller than usual, was not verified. The corrective action was completed on 3/23/2014 by your contract manufacturer but an incoming inspection of measuring the hole diameter was not performed on the next lot of incoming circumcision clamps, invoice [redacted] received on 4/16/14.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Marc S Neubauer, Investigator	06/17/2014

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OBSERVATION 3

Procedures for acceptance of incoming product have not been adequately established.

Specifically, the Quality Assurance Incoming Inspection Procedure (no date) states for incoming inspection of the [redacted] circumcision clamps: "Pull 2% of product group for lot sampling procedures." This procedure was not adequately implemented. 5 of 13 incoming inspection documents, Inspection Check List for Circumcision Clamps, reviewed for the circumcision clamp from 2013 to 2014 were inspected at less than 2%. This checklist includes all dimensional analysis (range of diameter of hole, length of T-part, etc.).

Invoice MDC/SD/20014/11, Lot size [redacted], inspected = 0, percentage inspected = 0%.
Invoice MDC/SD/20014/6, Lot size [redacted], inspected = 14, percentage inspected = 1.6%.
Invoice MDC/SD/20014/3, Lot size [redacted], inspected = 0, percentage inspected = 0%.
Invoice MDC/SD/20014/2, Lot size [redacted], inspected = 0, percentage inspected = 0%.
Invoice MDC/SD/20013/10, Lot size [redacted], inspected = 0, percentage inspected = 0.73%.

OBSERVATION 4

Procedures have not been established to control product that does not conform to specified requirements.

Specifically, procedures have not been established to address the identification, documentation, evaluation, segregation and disposition of nonconforming product from incoming inspections.

OBSERVATION 5

Procedures for management review have not been established.

Specifically, procedures to describe how and when management review meetings will be conducted have not been established.

Management review meetings to review the suitability and effectiveness of the quality system have not been performed.

A Management Representative has not been appointed.

OBSERVATION 6

Document control procedures have not been established.

Specifically, procedures have not been established to control the review and approval of SOPs and documents found in the design history file for the [redacted]

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The following SOPs lack the document approval date and signature of the approving official.

[redacted]

OBSERVATION 7

Procedures for training and identifying training needs have not been established.

Specifically, there are no training records for the Quality Control/Inventory Management worker and Quality Control Manager.

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.
Observation 7:	Promised to correct.		

*** DATES OF INSPECTION:**
06/10/2014(Tue), 06/17/2014(Tue)

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