DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderly Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/11/2016-7/13/2016
	FEI NUMBER 3004892080

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael A. Knox , President & C.E.O.

FIRM NAME	STREET ADDRESS
Ultroid Technologies, Inc.	3140 W Kennedy Blvd Suite 103
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tampa, FL 33609-3175	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

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

Specifically, you have not implemented your current Corrective and Preventive Action procedure, QOP-85-04, Rev 1.00. For example:

A. You have not fully implemented Section 6.3.3 and 6.3.4 of your current procedure, requiring investigation to identify the underlying cause(s) for the identified problem(s).

i. Your records for corrective actions 16-001, 16-002, 16-003, and 16-004 were all initiated on or before 02/16/2016 and do not list any activities following your identification of the problem(s) found to require corrective action.

ii. Your records for corrective action 14-009 do not identify the underlying cause for the problem related to broken seals of the sterile barrier for the probe component of the Procedure Kit used with the Ultroid brand Hemorrhoid Management System device.

iii. Your records for corrective action 14-008 do not clearly demonstrate that user errors were the cause for cable-connection problems and the resulting power-up problems reported for the Ultroid brand Hemorrhoid Management System device.

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B. You have not implemented Section 6.1.4 of your current procedure, requiring evaluation of complaints and allegations of poor quality alleged against your Ultroid brand Hemorrhoid Management System device.

i. You have no documented evaluation of Complaint Records #1- #13 listed on your Customer Feedback/Complaint Log, F-720-005-A.

ii. You have no documented evaluation of Customer Survey Form, F-720-001-C, dated June 2, 2011, listing the lowest possible rating for quality of the device.

C. You have not implemented Section 6.5 of your current procedure, requiring verification and/or validation that the corrective actions were effective.

i. You do not have records demonstrating it was effective to change the pouch for the probe component of the Procedure Kit used with the Ultroid brand Hemorrhoid Management System device, in order to prevent broken pouch seals addressed under corrective action 14-009, dated 05/30/2014.

ii. You do not have records demonstrating it was effective to change how the cable for the hand piece connects to the base of the Ultroid brand Hemorrhoid Management System device, in order to prevent the power-on problems reported against the device addressed under corrective action 14-008, dated 05/30/2014.

Corrective action deficiencies were listed on a Warning Letter issued to the firm 08/27/2015 and listed to the firm during the FDA inspections of 05/06-09/2008, 02/04-09/2010, 02/03-12/2014, and 04/06-15/2015.

OBSERVATION 2

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Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically,

A. You have not implemented Section 1.2 of your current Supplier Evaluation and Monitoring procedure, QOP-74-01, Rev A, requiring that suppliers with poor quality history be issued corrective action requests. For example, you have not issued a corrective action request to your contract manufacturer located in (b) (4) regarding their lack of providing production records in a timely manner. This vendor did not supply production records in a timely manner during the FDA inspection of 04/06-15/2015 and during the current inspection.

B. You have not implemented Section 1.1 of your current procedure requiring a Framework record, QF-74-01-3 to be completed for every contract manufacturing organization (CMO) utilized by the firm. For example, you do not have a Framework record covering the contract manufacturer you use located in (b) (4) in order to list the requirements for environmental controls and/or monitoring associated with production of a component for the Procedure Kit used with the Ultroid brand Hemorrhoid Management System, although that component is (b) (4) . Additionally, previous sterilization loads for this component have not demonstrated elimination of all viable microorganisms.

Purchasing control deficiencies were listed on a Warning Letter issued to the firm 08/27/2015 and listed to the firm during the FDA inspections of 02/04-09/2010, 02/03-12/2014, and 04/06-15/2015.

OBSERVATION 3

There is no record maintained of a correction or removal action that was not required to be reported to FDA.

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Specifically,

A. You did not notify the Food and Drug Administration about your effort to contact customers in order to determine if Procedure Kits for the Ultroid brand Hemorrhoid Management System device, containing Lot# 100028 or Lot# 100044 of the probe component, were still held for sale. You do not have records documenting a description of the details leading to this effort to request inspection of Procedure Kit products, a description of the inspection requested, and a justification for not notifying the agency about this effort.

~~B. You were unable to locate and provide for review and copying the artwork records for the labels applied to your Ultroid brand Hemorrhoid Management System device.~~

OBSERVATION 4

Procedures for design change have not been adequately established.

Specifically, you have not implemented design change controls defined under your current Design and Development Control procedure, QOP-73-01, Rev A. For example:

A. You have no records covering review, verification and/or validation of a change to the pouch used as the sterile barrier for the probe used with the Ultroid Hemorrhoid Management System device and covered under CAPA #14-009, dated 05/30/2014.

B. You do not have records covering verification and/or validation of a change to the cable for the hand piece used with your Ultroid Hemorrhoid Management System device, covered under CAPA# 14-008, dated 05/30/2014, and under the record for design change Project #1001.

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Design change control deficiencies were listed on a Warning Letter issued to the firm 08/27/2015 and listed to the firm during the FDA inspections of 02/03-12/2014 and 04/06-15/2015.

OBSERVATION 5

The design history file does not demonstrate that the design was developed following the requirements of 21 CFR 820.

Specifically, you have not implemented your current Design and Development Control procedure, QOP-73-01, Rev A. For example:

A. You do not have records listing the design input requirements for your Ultroid brand Hemorrhoid Management System device defining requirements for the following:

i. Time and/or environmental conditions under which the Procedure Kit for the device may be maintained and ensure preservation of the sterile barrier for the probe component.

ii. Any requirements regarding the ability to disconnection/reconnection of the cable between the handpiece and the base of the device.

B. You do not have records covering validation of the design for your Ultroid brand Hemorrhoid Management System device demonstrating that the design meets users' needs for the following:

i. Time and/or environmental conditions under which the Procedure Kit for the device may be maintained and preserve the sterile barrier for the probe component.

ii. Labeling to inform users of the time and/or environmental conditions under which the probe component of the Procedure Kit used with the device might no longer be considered sterile.

C. You do not have records demonstrating verification that design outputs meet the design input requirements for the Ultroid brand Hemorrhoid Management System device.

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D. You do not have records for the Ultroid brand Hemorrhoid Management System demonstrating that you controlled transfer of the design for this device to production specifications.

Design control deficiencies were listed on a Warning Letter issued to the firm 08/27/2015 and listed to the firm during the FDA inspections of 02/04-09/2010, 02/03-12/2014, and 04/06-15/2015.

OBSERVATION 6

Procedures for quality audits have not been adequately established.

Specifically, you have not fully implemented your current Internal Quality Audits procedure, QOP-82-02, Rev A, or your previous Internal Audits procedure, Revision F. For example, you have not carried out an internal quality audit since May of 2013, although annual quality audits are required under both procedures.

Quality audit deficiencies were listed on a Warning Letter issued to the firm 08/27/2015 and listed to the firm during the FDA inspections of 05/06-09/2008, 02/04-09/2010, 02/03-12/2014, and 04/06-15/2015.

OBSERVATION 7

Required records are not maintained at a location that is reasonably accessible to responsible officials of the manufacturer and to employees of the FDA and were not made readily available for review and copying by the FDA.

Specifically,

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A. You were unable to access and make available for copying the production and labeling records for Ultroid brand Hemorrhoid Management System devices manufactured during (b) (4) and/or manufactured during (b) (4).

B. You were unable to access and make available for copying the production and labeling records for Lot# PK091615ISL of Procedure Pack devices, used with the Ultroid brand Hemorrhoid Management System devices, which were manufactured during (b) (4)

C. You were unable to locate and provide for review and copying the artwork records for the labels applied to your Ultroid brand Hemorrhoid Management System device.

Records availability deficiencies were listed on a Warning Letter issued to the firm 08/27/2015 and listed to the firm during the FDA inspection of 04/06-15/2015.

OBSERVATION 8

Procedures for management review have not been adequately established.

Specifically, you have not fully implemented your current Management Review procedure, QOP-56-01, Rev A, or your previous Management Responsibility procedure, P500, Rev E. For example, you have not conducted a management review since 04/15/2015, although annual management review is required under each of these procedures.

OBSERVATION 9

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The device history record does not demonstrate that the device was manufactured in accordance with the device master record and 21 CFR 820.

Specifically, you do not have records covering packaging, labeling, and final release for the Procedure Pack Kits, Lot# PK091615-ISL120256. Further, the label records maintained on file do not demonstrate that all of these devices list the correct/complete manufacturing code.

OBSERVATION 10
Document control procedures have not been adequately established.

Specifically, you have not fully implemented your current Control of Documents procedure, QOP-42-01, Rev A. For example,

A. Your current written quality system procedures, including the Design & Development Control procedure, QOP-73-01, the Corrective and Preventive Action procedure, QOP-85-04, and the Supplier Evaluation and Monitoring procedure, QOP-74-01, are not signed as approved for use, and you do not have a signed ECN on file covering these quality system procedures, as required under Section 4.1 of the QOP-42-01 procedure.

B. Your previous written Corrective and Preventive Action procedure, QOP-85-04, Rev A, is not marked "OBSOLETE" and is not filed separately from other quality system documents, as required under Section 9.2 of the QOP-42-01 procedure. Further, this obsolete Corrective and Preventive Action procedure was initially identified as your current procedure.

Annotations to Observations

Observation 1: *Promised to correct within 12 Weeks*
Observation 2: *Promised to correct within 12 Weeks*

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Observation 3: *Promised to correct within 12 Weeks*
Observation 4: *Promised to correct within 12 Weeks*
Observation 5: *Promised to correct within 12 Weeks*
Observation 6: *Promised to correct within 12 Weeks*
Observation 7: *Promised to correct within 12 Weeks*
Observation 8: *Promised to correct within 12 Weeks*
Observation 9: *Promised to correct within 12 Weeks*
Observation 10: *Promised to correct within 12 Weeks*

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."