510(k) Summary
for the Opus KSD, Inc.
SubQ It!™ Bioabsorbable Skin Closure System
(*per 21CFR 807.92*)

1. SUBMITTER/510(K) HOLDER

Opus KSD, Inc.
210 Worcester Rd
Peacham, VT 05862
Contact Person: Charles H. Rogers, C.E.O.
Telephone: +1.781.929.7406

Date Prepared: May 21, 2013

2. DEVICE NAME

Proprietary Name: SubQ It!™ Bioabsorbable Skin Closure System
Common/Usual Name: Skin staples and stapler
Classification Name: Staple, implantable

3. PREDICATE DEVICES

Incisive Surgical, INSORB™ Absorbable Staple (Multiple 510(k)'s e.g. K024117, K033602, K061784, K090159, K120373)

4. DEVICE DESCRIPTION

The SubQ It!™ Bioabsorbable Skin Closure System comprises bioabsorbable fasteners made of 82/18 L-lactide/Glycolide copolymer, a well-established material for resorbable medical devices. The fasteners have two legs with barbed tips (4.3mm long, 0.88mm diameter and spaced 2.75mm center-to-center). The fasteners are inserted using the SubQ It!™ Stapler.

5. INDICATION FOR USE/INTENDED USE

The SubQ It!™ Bioabsorbable Skin Closure System is intended for use in humans for abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery for the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The SubQ It!™ Bioabsorbable Skin Closure System is substantially equivalent to the INSORB™ Absorbable Staple when used with the INSORB Subcuticular Skin Stapler manufactured by Incisive Surgical, Inc. The intended use is the same, the fasteners are similar in size and material, with similar strength and mass. Both the new device and the predicate are sterilized by gamma radiation and pre-loaded into a manual stapler, packaged for single patient use.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The SubQ It!™ Bioabsorbable Skin Closure System was tested side-by-side with the INSORB™ device in 7cm long incisions in a GLP compliant porcine animal model for 90 days. Data show no significant differences between the SubQ It!™ and the predicate device.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Clinical testing has not been performed.

9. SUMMARY OF OTHER INFORMATION

The SubQ It!™ Bioabsorbable Skin Closure System was also tested in 1 cm and 2 cm incisions in a GLP compliant porcine animal model, subjected to bench tests, shelf-life study of mechanical performance, and packaging tests. These studies demonstrate the safety and effectiveness of the SubQ It!™ Bioabsorbable Skin Closure System for its intended use. Additionally, the finished, sterilized product met requirements of biocompatibility tests.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Based on descriptive information and test results, Opus KSD, Inc. has determined that the SubQ It!™ Bioabsorbable Skin Closure System is substantially equivalent to the INSORB™ Absorbable Staple manufactured by Incisive Surgical, Inc., that differences between the two products are minor, and raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

Opus KSD Incorporated
% Ms. Rosina Robinson, RN, Med, RAC
Aptiv Solutions
62 Forest Street, Suite 300
Marlborough, Massachusetts 01752

Re: K131563
Trade/Device Name: SubQ It!™ Bioabsorbable Skin Closure System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: February 20, 2014
Received: February 21, 2014

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131563

Device Name
SubQ It!™ Bioabsorbable Skin Closure System

Indications for Use *(Describe)*
The SubQ It!™ Bioabsorbable Skin Closure System is intended for use in humans for abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery for the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S
2014.04.09 08:31:37 -04'00'

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