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

August 3, 2016

Scion Medical Technologies, LLC
Louis Li
QA/RA Manager
4613 West Chester Pike
Newton Square, PA 19073

Re: K161234
Trade/Device Name: CASSI II Rotational Core Biopsy System
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: KNW
Dated: June 29, 2016
Received: July 5, 2016

Dear Louis Li:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K161234

Device Name

CASSI II Rotational Core Biopsy System

Indications for Use *(Describe)*

The Cassi Rotational Core Biopsy Device is indicated for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes, and various soft tissue tumors. It is not intended for use in bone.

The Cassi Device is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histological examination with partial or complete removal of the imaged abnormality. The extent of a histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality (e.g. malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Summary
as required by 21 CFR 807.92(a)

A) Submitted by: Scion Medical Technologies, LLC

4613 West Chester Pike
Newtown Square, Pennsylvania 19073
USA

Official Contact: Louis Li QA/RA Manager

Telephone: (610)533-3577
Fax: (484)428-3187
E-mail: louisli@scionmedtech.com

B) Proprietary Name: CASSI™ II Rotational Core Biopsy System
Common Name: Gastroenterology-urology biopsy instrument

Device Class: Class II, 21 CFR 876.1075
Regulation and
Classification name: Instrument, Biopsy

Product code: KNW

Classification panel: Gastroenterology-urology

C) Predicate: CASSI™ II Rotational Core Biopsy System, with the
CASSI QuadPoint™ Disposable K123606 Cleared on March 1st, 2013

D) Date Prepared: April 28, 2016

E) Device Description

The proposed CASSI II Rotational Core Biopsy System consists of the following primary components: a fully integrated CASSI biopsy handle, a valve block, battery, cryogen, a Cassi biopsy needle (CASSI biopsy needle comprised of a sticking needle and cutting cannula/piston assembly), and a sample collection tray. The sticking needle is operated by CASSI biopsy handle and uses cold temperatures at its tip to engage the tissue to be sampled. The cutting cannula is coaxially mounted around the sticking needle and is used to core the tissue specimen. The cutting cannula is available in two sizes (10 and 12 gauge).

The proposed CASSI biopsy handle are minor design evolution of the predicate CASSI II biopsy handle. The proposed CASSI II biopsy needle unit assembly remains unchanged from the predicate CASSI II biopsy needle unit assembly.

The proposed CASSI II system uses one control unit handle and allows for multiple, single patient use, biopsy needle units to operate with the handle (See Figure 1, below), in the very same manner as the predicate CASSI II device. The principles of operation

for the proposed CASSI™ II Rotational Core Biopsy System and the predicate CASSI II system remain unchanged.

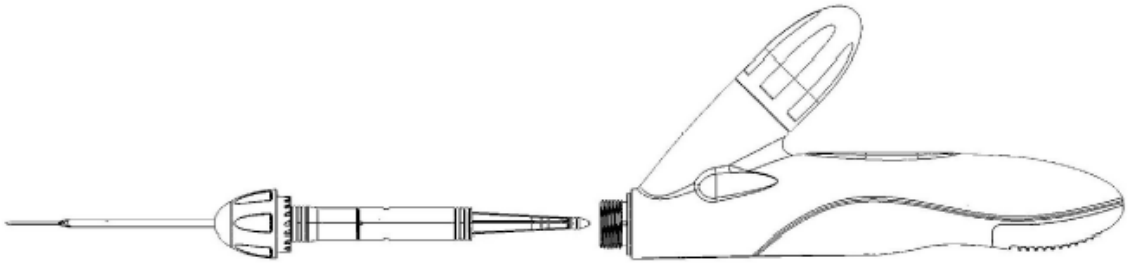


Figure 1: Proposed CASSI™ II Rotational Core Biopsy System and predicate CASSI II Rotational Core Biopsy System – reusable handle and disposable biopsy needle unit assembly.

This submission is for changing contract manufacturer from Sanarus Technologies (Address:7068 Koll Center Parkway,Suite 425, Pleasanton, CA 94566 U.S.A.) to Scion Technologies Jiangsu Ltd (Address: Building G32,China Medical City,Taizhou,Jiangsu P.R.China, 225300) and sterilizer from Sterigenics (Address: 2311 Lincoln Ave. Hayward, CA 94545 U.S.A.) to Shanghai JPY TECH. CO.,LTD (Address:No 1168, Huijin Rd. Shanghai Qingpu Industrial Zone. Shanghai P.R.China 201707), but the sterilization method and sterility assurance level of 10-6 remain exactly same.

Scion Medical Technologies, LLC moved the office from 90 Oak Street Newton, MA 02464 U.S.A to 4613 West Chester Pike Newtown Square, Pennsylvania 19073 USA

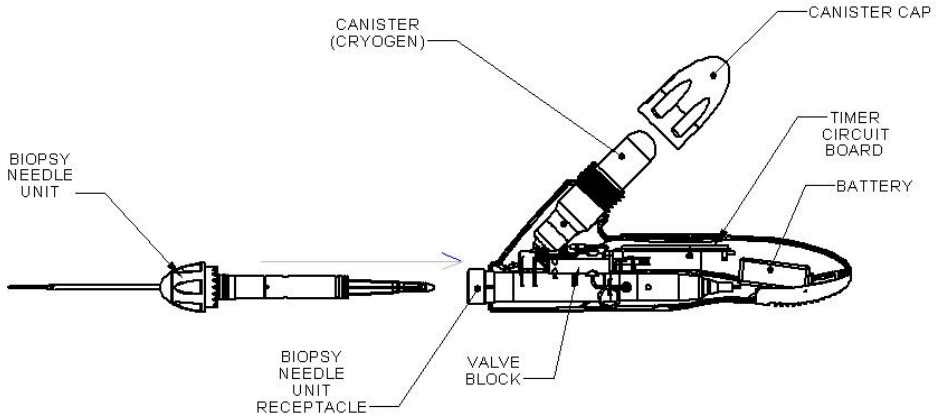
Additionally, minor design evolutions of the predicate CASSI II biopsy handle are as follows:

1. Added PCBA coating. The purpose is to mitigate the possibility of moisture or chemical contaminating the components of the board and protect the component of the board (e.g. ESD).

2. Add JB weld adhesive to the valve body (See Figure 2). The purpose is to enhance the valve body strength and mitigate the risk of valve crack caused by thermal shock.

3. Changed the shelf life of CASSI QuadPoint disposable biopsy needle unit from 1 year to 3 years.

Figure 2: Proposed CASSI II Rotational Core Biopsy System and the predicate CASSI II device system configuration.



F) Intended Use/Indications For Use:

The Indications for Use, of the proposed CASSI II Rotational Core Biopsy System remain unchanged from the cleared CASSI II Rotational Core Biopsy System predicate device (K123606).

The Cassi Rotational Core Biopsy System is indicated for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes, and various soft tissue tumors. It is not intended for use in bone.

The Cassi Rotational Core Biopsy System is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histological examination with partial or complete removal of the imaged abnormality. The extent of a histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality (e.g., malignancy).
When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

G) Substantial Equivalence Comparison and Discussion

In summary, Scion Medical Technologies, LLC believes that the proposed changes, as described in this submission, do not raise any new or significant questions of safety and efficacy and is substantially equivalent to the predicate Scion Medical Technologies, LLC CASSI II Rotational Core Biopsy System cleared on March 1st, 2013 (K123606)

H) Compliance with Design Controls

The results of assessment of the change to the CASSI™ II Rotational Core Biopsy System, conducted under Design Controls, support that the new offering is substantially equivalent to the predicate device delivery system.

Compliance with Standards:

ISO 15223-1:2012, Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

ISO 14971: 2007, Medical devices - Application of risk management to medical devices

EN 1041:2008 Information supplied by the manufacture of medical devices

ISO11137-1:2006 Sterilization of health care products —Radiation —Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices