November 22, 2019

Intelligent Endoscopy
Melissa Clark
President
4740 Commercial Park Ct, Suite 1
Clemmons, NC 27012

Re: K190512
Trade/Device Name: SmartBand EMR Kit (SB-EMR-K, SB-EMR-K-12)
SmartBand EMR Pack (SB-EMR-P, SB-EMR-P-12)
SmartSnare EMR Hexagonal Snare
(SS-230-1 or packaged with Kit)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: FDI
Dated: May 2, 2019
Received: May 6, 2019

Dear Melissa Clark:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, Ph.D.
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190512

Device Name

SmartBand® EMR Kit (SB-EMR-K, SB-EMR-K-12)
SmartBand® EMR Pack (SB-EMR-P, SB-EMR-P-12)
SmartSnare™ EMR Hexagonal Snare (SS-230-1 or packaged with Kit)

Indications for Use *(Describe)*

The SmartBand® EMR Device is intended for endoscopic mucosal resection in the upper GI tract.

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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Intelligent Endoscopy

510(k) Summary

Manufacturer: Intelligent Endoscopy, LLC
4740 Commercial Park Ct, Suite 1
Clemmons, NC 27012
Establishment Registration Number: 3011324403

Contact: Melissa Clark
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Intelligent Endoscopy, LLC
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Date Prepared: February 27, 2019

Trade Name: SmartBand® EMR Kit (SB-EMR-K, SB-EMR-K-12)
SmartBand® EMR Pack (SB-EMR-P, SB-EMR-P-12)
SmartSnare™ EMR Hexagonal Snare (SS-230-1 or packaged with Kit)

Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Product Code: FDI
Classification: Class II
Review Panel: Gastroenterology / Urology
Predicate Device: Captivator™ EMR Device (K140726)

Device Description:
The SmartBand® EMR Device is an endoscopic mucosal resection device that is provided as a Kit or a Pack that is designed for ligation assisted endoscopic mucosal resection (EMR) in the upper gastrointestinal (GI) tract. The SmartBand® EMR Kit consists of the SmartBand Ligator Kit, supplied non-sterile and the SmartSnare™ EMR Hexagonal Snare, supplied sterile. The ligator kit contains a ligation handle, loading device, connector tube, and a cylindrical barrel with 5 bands separated by a deployment cord. The SmartBand® EMR Pack consists of a cylindrical barrel with 5 bands separated by a deployment cord, which can be used when more bands are needed to complete the procedure.

Indications for Use:
The SmartBand® EMR Device is indicated for endoscopic mucosal resection in the upper GI tract.

Technological Characteristics:
The SmartBand® EMR Device is an accessory to be used with an appropriate endoscope of the gastroenterologist's choice. The deployment cord is passed retrograde through the accessory channel of the endoscope using the loading device and then assembled to the ligation handle. The cylindrical barrel with 5 bands, attaches to the distal end of the endoscope. When the handle is turned, a band is deployed around the mucosal tissue creating a pseudopolyp. The ligation handle allows for the passage of the electrosurgical snare through the accessory channel of the endoscope. The

SmartSnare™ wire loop is placed around the pseudopolyp and the targeted tissue is removed using electrocautery. The SmartBand® EMR Device shares substantially equivalent design features and function with the predicate.

The SmartBand® EMR Device has the same intended use and is placed using the same methodology as the predicate device. The SmartBand® EMR Device and the predicate device use a barrel / cap to suction and capture tissue during an endoscopic mucosal resection procedure, band the tissue into a pseudopolyp, and use an electrosurgical snare to resect the tissue. The SmartBand® EMR Device and the predicate device are both used to perform ligation-assisted endoscopic mucosal resections.

Performance Testing Summary:
The SmartBand® EMR Kit is provided in a box with two packaged components. The SmartBand® Ligator Kit, provided non-sterile, and the SmartSnare™ EMR Hexagonal Snare, provided sterile. The SmartBand® EMR Pack is provided non-sterile in a pouch. All components have been performance bench tested to ensure safe and effective function of the device. The non-clinical comparative performance testing successfully determined that the SmartBand® EMR Device is substantially equivalent to the predicate. This testing included but was not limited to system suction delivery efficiency with the snare, band ultimate tensile force, and snare loop to pull wire tensile strength.

The SmartSnare™ EMR Hexagonal Snare is provided with the Kit in a separate sterile pouch. Testing according to EN ISO 11135-1 and EN ISO 11138-2, *sterilization of health care products*, verifies that the ETO sterilization method and parameters that are used to sterilize the SmartSnare™ EMR Hexagonal Snare. The predicate device also uses ETO sterilization.

Biocompatibility Testing Summary:
Representative production units of The SmartBand® EMR Device were submitted to complete biocompatibility studies in accordance to ISO 10993-1. The patient contacting components of the device (the barrel, bands, cord and snare) were subjected to and showed acceptable results to Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, and USP Physicochemical testing.

Conclusion Summary of Substantial Equivalence:
There have been no prior submissions for the subject device. Intelligent Endoscopy has demonstrated in this original Traditional 501(k) that the SmartBand® EMR Device is substantially equivalent to the Captivator™ EMR Device (K140726) that is currently available in the market.