DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 17, 2017

Crospon Ltd.
Paul Dryden
Consultant
24301 Woodsage Dr.
Bonita Springs, Florida 34135

Re: K170833
Trade/Device Name: FLIP Topography
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: Class II
Product Code: FFX
Dated: March 16, 2017
Received: March 20, 2017

Dear Paul Dryden:

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,

Charles Viviano -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)*

K170833

Device Name

EndoFLIP® System with FLIP Topography module

Indications for Use *(Describe)*

The EndoFLIP® System is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

The EF-325 series of catheters can make pressure and dimensional measurements in the esophagus, pylorus, and anal sphincters; whereas the BF-325 series and EF-825 catheters can make dimensional measurements in the esophagus, pylorus, and anal sphincters. The EF-620 catheter can make dimensional measurements in the esophagus.

Other indications for use include:

- To estimate the size of a stoma produced by a gastric band (all EndoFLIP® catheters)

- For use as an adjunct to a bougie for measuring the size of a gastric sleeve created during bariatric surgery, where it is suitable for diameter measurements for 22 to 60Fr sleeves (EF-620 catheter)

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

XX 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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Company: Crospon Ltd.
Galway Business Park
Dangan, Galway, Ireland
Tel: +011 [353] (91) 519882

Official Contact: John O'Dea PhD - CEO

Proprietary or Trade Name: EndoFLIP® System with FLIP Topography module

Common/Usual Name: Gastrointestinal motility monitoring system

Classification Name: FFX

Device: FLIP Topography module

Modified Device: K160725 – EndoFLIP® System – Crospon Ltd.

Device Description:
The modification to the EndoFLIP® System is the addition of display functionality. This functionality is software and is referred to as the FLIP Topography module which is a supplemental accessory.

The addition of the supplemental accessory FLIP Topography module does not modify the predicate EndoFLIP® System or change the intended use of the device. This modification does not alter the fundamental scientific technology; the EndoFLIP® System algorithm or change the hardware and accessories associated with the EndoFLIP® System.

As there are no changes in hardware or software that will impact performance, there is no need to validate the changes through a clinical investigation.

Modification:
The modification to the EndoFLIP® System is the addition of display functionality. This functionality is software and is named the FLIP Topography module. FLIP Topography module is software which runs on an off-the-shelf PC that connects to the EndoFLIP® via a cable and displays the data on a larger screen.

FLIP Topography displays the traditional EndoFLIP® data plus FLIP Topography adds historical data graphs (live data for the last 40 seconds) for use by the clinician.

Indications for Use:
The EndoFLIP® System is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

The EF-325 series of catheters can make pressure and dimensional measurements in the esophagus, pylorus, and anal sphincters; whereas the BF-325 series and EF-825 catheters can make dimensional measurements in the esophagus, pylorus, and anal sphincters. The EF-620 catheter can make dimensional measurements in the esophagus.

Other indications for use include:

- To estimate the size of a stoma produced by a gastric band (all EndoFLIP® catheters)

- For use as an adjunct to a bougie for measuring the size of a gastric sleeve created during bariatric surgery, where it is suitable for diameter measurements for 22 to 60Fr sleeves (EF-620 catheter)

The indications for use are unchanged.

Patient Population:
Patients with symptoms consistent with gastrointestinal motility disorders.

Environment of Use:
Hospitals, Physician offices.

Contraindications:
The EndoFLIP® System is contraindicated where endoscopy is contraindicated.

The EndoFLIP® System is contraindicated for use in patients with actively bleeding varices in the esophagus.

Predicate Device Comparison
The EndoFLIP® System with FLIP Topography module is compared to the EndoFLIP® System in the device comparison table below.

Summary of Modifications:
The modification to the EndoFLIP® System is the addition of display functionality; this functionality is software and is named the FLIP Topography module. FLIP Topography is software which runs on an off-the-shelf PC that connects to the EndoFLIP® via a cable and displays the data on a larger screen.

Verification and Validation Activities
Verification activities for the modification were performed and the results demonstrated that the predetermined acceptance criteria were met. These verification activities included:

- Data acquisition
- Display characteristics (labels, accuracy, etc.)
- Data management
- Communication

Comparison to Predicate

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	EndoFLIP® System with FLIP Topography module	**Unmodified Predicate EndoFLIP® System K160725**
Attributes		
Indications for Use	The EndoFLIP® System is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders. The EF-325 series of catheters can make pressure and dimensional measurements in the esophagus, pylorus, and anal sphincters; whereas the BF-325 series and EF-825 catheters can make dimensional measurements in the esophagus, pylorus, and anal sphincters. The EF-620 catheter can make dimensional measurements in the esophagus. Other indications for use include: • To estimate the size of a stoma produced by a gastric band (all EndoFLIP® catheters) • For use as an adjunct to a bougie for measuring the size of a gastric sleeve created during bariatric surgery, where it is suitable for diameter measurements for 22 to 60Fr sleeves (EF-620 catheter)	The EndoFLIP® System is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders. The EF-325 series of catheters can make pressure and dimensional measurements in the esophagus, pylorus, and anal sphincters; whereas the BF-325 series and EF-825 catheters can make dimensional measurements in the esophagus, pylorus, and anal sphincters. The EF-620 catheter can make dimensional measurements in the esophagus. Other indications for use include: • To estimate the size of a stoma produced by a gastric band (all EndoFLIP® catheters) • For use as an adjunct to a bougie for measuring the size of a gastric sleeve created during bariatric surgery, where it is suitable for diameter measurements for 22 to 60Fr sleeves (EF-620 catheter)
Anatomical Sites	Esophagus, stomach, pylorus, and anal sphincters	Esophagus, stomach, pylorus, and anal sphincters
Environments of use	Hospitals, Physician offices	Hospitals, Physician offices
Patient Population	Patients with symptoms consistent with gastrointestinal disorders Patient undergoing gastric band surgery and post-operative band adjustment	Patients with symptoms consistent with gastrointestinal disorders Patient undergoing gastric band surgery and post-operative band adjustment

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	EndoFLIP® System with FLIP Topography module	**Unmodified Predicate EndoFLIP® System K160725**
Contraindications	The EndoFLIP® System is contraindicated where endoscopy is contraindicated. The EndoFLIP® System is contraindicated for use in patients with actively bleeding varices in the esophagus.	The EndoFLIP® System is contraindicated where endoscopy is contraindicated. The EndoFLIP® System is contraindicated for use in patients with actively bleeding varices in the esophagus.
Principle of Operation	The catheter is positioned in the desired location one volume setting and inflation rate to be made. There are up to ten isovolumetric steps which are pre-programmed. These steps are programmed in terms of the volume to be delivered and the time to pause between each step. Alternatively the system can be programmed to allow the patient to decide when the next step commences.	The catheter is positioned in the desired location one volume setting and inflation rate to be made. There are up to ten isovolumetric steps which are pre-programmed. These steps are programmed in terms of the volume to be delivered and the time to pause between each step. Alternatively the system can be programmed to allow the patient to decide when the next step commences.
FLIP Topography	Software that displays EndoFLIP® data on a larger screen and provides a historical graph that shows readings over time.	EndoFLIP® displays data on its integrated screen. Does not have a historical graph option to show readings over time.
Data Recording	Data is saved internally and can be exported to a USB mass storage device or printed to an attached USB printer	Data is saved internally and can be exported to a USB mass storage device or printed to an attached USB printer
Electrical Safety	The addition of the medical grade computer does not change the electrical safety from K120997.	No change in device from Crospon - K120997
Computer	FLIP Topography runs on an off-the-shelf medical grade computer	EndoFLIP® is not run on a PC
Biocompatibility	This modification does not affect the accessories and materials in patient contact	Identical to Crospon - K092850
Compatibility With The Environment And Other Devices	FLIP Topography module is only to be connected to the EndoFLIP® system	N/A
Performance	No performance testing for a display device only.	N/A

Differences Between Other Legally Marketed Predicate Devices
The Crospon EndoFLIP® System with FLIP Topography module is viewed as substantially equivalent to the predicate device because: The EndoFLIP® System with FLIP Topography uses the identical technology and has the identical indications for use. The differences that exist between the devices do not raise new concerns of safety or effectiveness.

Indications –
The indications for use are identical.

Prescriptive – Both the EndoFLIP® with FLIP Topography module and the predicate EndoFLIP® System are prescriptive.

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Design and Technology – The EndoFLIP® System with FLIP Topography module has equivalent design, features, and identical technology to the predicate.

Performance and Specifications – The EndoFLIP® System with FLIP Topography module has the equivalent specifications of performance as the predicate.

Compliance with standards – The modification of adding the supplemental accessory EndoFLIP® System with FLIP Topography module does not change the compliance to IEC 60601-1 and IEC 60601-1-2.

Materials –
There are no changes in materials.

Patient Population –
The patient population is unchanged.

Non-Clinical Testing Summary:
The modification required verification activities related to the software. The predicate EndoFLIP® System had undergone bench tests as part of previous submissions. EndoFLIP® System met all requirements specifications and standards requirements as presented in K092850.

Substantial Equivalence Conclusion
Crospon maintains that the EndoFLIP® System with FLIP Topography module is substantially equivalent to the EndoFLIP® System in indications for use, patient population, environment for use, technology characteristics, specifications / performance and compliance with international standards. The addition of the FLIP Topography module as a supplemental accessory, as such, does not change the indications of the unmodified EndoFLIP® System as cleared under K160725. As presented the performance features of the FLIP Topography module as outlined in the above table and discussed in the comparison to support substantial equivalence.