DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 1, 2016

Crospon Ltd.
Paul E. Dryden
Consultant
Galway Business Park, Dangan
Galway
Ireland

Re: K160725
Trade/Device Name: EndoFLIP® System
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: II
Product Code: FFX
Dated: March 31, 2016
Received: April 4, 2016

Dear Paul E. 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 yours,

Benjamin R. Fisher -S

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)*
K160725

Device Name
EndoFLIP® System

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)*

☒ 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
Official Contact:	John O'Dea PhD
Proprietary or Trade Name:	EndoFLIP® System
Common/Usual Name:	Gastrointestinal motility monitoring system
Classification Name:	FFX
Device:	EndoFLIP® System
Predicate Device:	K991288 – G&J Electronics, Distender Series II Barostat
Reference Devices:	K120997 – EndoFLIP® system – Crospon Ltd. K092850 – EndoFLIP® system – Crospon Ltd.

Device Description:
The EndoFLIP® system and its accessory catheters are identical to the reference Crospon EndoFLIP® K120997. The proposed modifications to the EndoFLIP® system is to expand the anatomical locations to encompass the measurement of pressures and dimensions in the esophagus, pylorus, and anal sphincters.

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)

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.

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	Distender Series II Barostat **G&J Electronics** **K991288**	**EndoFLIP®** **Crospon** **K120997 / K092850 / K102214**	**Proposed** **EndoFLIP®** **Expanded Indications**
Indications for Use	The Distender Series II Dual Drive Barostat device with the Protocol Plus software is an electro-pneumatic device used for volume / pressure measurement in the alimentary tract. This device 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 EndoFLIP® system is indicated for use in a clinical setting as a pressure and dimension measurement device and for balloon distension provocation testing in the esophagus. Indicated for use in patients fitted with a gastric band. The device is intended to estimate the size of the stoma produced by the gastric band Indicated for use as an adjunct to a bougie for measuring the size of a gastric sleeve created during bariatric surgery. It is suitable for diameter measurements for 22 to 60French sleeves	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)

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	Distender Series II Barostat G&J Electronics K991288	**EndoFLIP® Crospon K120997 / K092850 / K102214**	**Proposed EndoFLIP® Expanded Indications**
Anatomical Sites	Alimentary tract Esophagus, stomach, small bowel, colon and rectum	Esophagus, Stomach	Esophagus, stomach, pylorus, and anal sphincters
Environments of use	Hospitals, Physician offices	Hospitals, Physician offices	Hospitals, Physician offices
Patient Population	Patients with symptoms consistent with gastrointestinal motility disorders	Patients with esophageal disorders (K120997) Patient undergoing gastric band surgery and post-operative band adjustment (K092850)	Patients with symptoms consistent with gastrointestinal disorders Patient undergoing gastric band surgery and post-operative band adjustment
Contraindications	Not stated	The EndoFLIP® System is contraindicated where endoscopy is contraindicated.	The EndoFLIP® System is contraindicated where endoscopy is contraindicated.
Principle of Operation	Pneumatic device that maintains an isobaric pressure or isovolumetric volume within a balloon. Records volume and pressure changes during the protocol.	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.

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	Distender Series II Barostat G&J Electronics K991288	**EndoFLIP® Crospon K120997 / K092850 / K102214**	**Proposed EndoFLIP® Expanded Indications**
	Pressure sensor in the device is connected to the balloon via a measurement line.	Pressure sensor in the catheter balloon. D_{est} electrodes are located at 16 points along the catheter inside a balloon. The balloon is placed such that its midpoint is located in the esophagus. (K120997) The balloon is placed such that its midpoint is located in a stoma within a stomach fitted with a gastric band. (K092850)	Pressure sensor in the catheter balloon. D_{est} electrodes are located at 16 points along the catheter inside a balloon. The balloon is placed such that its midpoint is located in the area to be measured.
Data Recording	4 channels of data can be recorded on a chart recorder	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	Not stated	IEC60601-1 2nd Ed. + Am.1 + Am.2	No change in device from K120997
Biocompatibility	User sources balloons and tubing.	All materials have passed biocompatibility tests in accordance with ISO 10993-1 (K092850)	Identical to Crospon - K092850
Compatibility With The Environment And Other Devices	User sources balloons and tubing.	EndoFLIP operates with custom catheters only.	EndoFLIP operates with custom catheters only.
Performance	Volume range and resolution is dependent on the cylinder size used. Range available is 25ml to 1200ml. Resolution ranges from a piston step size of 0.181ml to 0.804ml	Balloon volume is controlled and delivered volume is displayed: Range: 0 to 50 mL Resolution: 1 mL	Balloon volume is controlled and delivered volume is displayed: Range: 0 to 50 mL Resolution: 1 mL

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Substantial Equivalence

The EndoFLIP® system with the expanded indications for use is viewed as substantially equivalent to the predicate and reference devices presented above. In summary we have found that the following key elements support a determination of substantially equivalent:

Indications –
The proposed indications for use are similar to the predicate, G&J Barostat K991288 when expanded to include the alimentary tract.

The other indications for use are identical to the reference, Crospon EndoFLIP® system, K120997
Discussion – The inclusion of the alimentary tract is consistent with the predicate K991288 Distender Series II Dual Drive Barostat and a subset of which are already within the scope of the current EndoFLIP® clearances.

Environment of Use –
The proposed environments of use are identical to the predicate, K991288 Distender Series II Dual Drive Barostat and reference EndoFLIP® K120997 / K092850.
Discussion – There have been no changes in the environments of use.

Patient Population –
The proposed patient population is patients with gastrointestinal motility disorders, identical to the predicate K991288 Distender Series II Dual Drive Barostat and reference EndoFLIP® K120997 which list patients with symptoms consistent with gastrointestinal disorders, which are equivalent.
Discussion – There have been no changes in the patient population.

Technology / Design / Features –
The technology is identical to the predicate EndoFLIP® systems (K092850) with no hardware or software changes.
Discussion – There have been no changes in the proposed device vs. the reference devices.

Materials –
There are no material changes from the predicate K092850.
Discussion – The identical accessory catheters are used therefore there have been no changes in the materials in patient contact.

Performance Specifications –
There are no design changes to the system or catheters and therefore no change in performance.
Discussion – There have been no changes in the performance specification vs. the reference devices.

Performance Testing – Bench
No comparative bench testing was required as there are no design changes to the system or catheter.

Performance Testing – Clinical
Independent clincial studies have been performed for the cited anatomical locations in the indictaions for use. There are:

1. Evaluation of anal sphincter resistance and distensibility in healthy controls using EndoFLIP. Alqudah MM, Gregersen H, Drewes AM, McMahon BP, Neurogastroenterol Motil. 2012:24(12) e591-9
2. Distensibility of the anal canal in patients with systemic sclerosis: A study with the Functional Lumen Imaging Probe. Fynne L, Luft F, Gregersen H, Buntzen S, Lundby L, Lundager F, Laurberg S, Krogh K., Colorectal Dis. 2013:15(1) e40-7
3. Functional luminal imaging probe: a new technique for dynamic evaluation of mechanical properties of the anal canal. Luft F, Fynne L, Gregersen H, Lundager F, Buntzen S, Lundby L, Laurberg S, Krogh K., Tech Coloproctol. 2012:16(6) 451-7
4. Do endoflip assessments of anal sphincter distensibility provide more information on patients with fecal incontinence than high-resolution anal manometry? Gourcerol G, Granier S, Bridoux V, Menard JF, Ducrotté P, Leroi AM., Neurogastroenterol Motil. 2015 Dec 15. doi: 10.1111/nmo.12740. [Epub ahead of print]
5. Distensibility of the anal canal in patients with idiopathic fecal incontinence: a study with the Functional Lumen Imaging Probe. Sørensen G1, Liao D, Lundby L, Fynne L, Buntzen S, Gregersen H, Laurberg S, Krogh K., Neurogastroenterol Motil. 2014 Feb;26(2):255-63.
6. Impaired fasting pyloric compliance in gastroparesis and the therapeutic response to pyloric dilatation. Gourcerol G, Tissier F, Melchior C, Touchais JY, Huet E, Prevost G, Leroi AM, Ducrotte P. Aliment Pharmacol Ther. 2014 Dec 19. doi: 10.1111/apt.13053. [Epub ahead of print]
7. Assessing pyloric sphincter pathophysiology using EndoFLIP in patients with gastroparesis. Malik Z, Sankineni A, Parkman HP., Neurogastroenterol Motil. 2015 Feb 24. doi: 10.1111/nmo.12522. [Epub ahead of print]
8. Evaluation of the pylorus with concurrent intraluminal pressure and EndoFLIP in patients with nausea and vomiting. Snape WJ, Lin MS, Agarwal N, Shaw RE. Neurogastroenterol Motil. 2016 Jan 27. doi: 10.1111/nmo.12772. [Epub ahead of print]
9. New measures of upper esophageal sphincter distensibility and opening patterns during swallowing in healthy subjects using EndoFLIP. J. Regan, M Walshe, N Rommel, J Tack, BP McMahon, Neurogastroenterol Motil. 2013 Jan;25(1):e25-34
10. 'Endoflip® evaluation of pharyngo-oesophageal segment tone and swallowing in a clinical population: a total laryngectomy case series'. Regan J, Walshe M, Timon C, McMahon BP., Clin Otolaryngol. 2015 Apr;40(2):121-9.
11. A new evaluation of the upper esophageal sphincter using the functional lumen imaging probe: a preliminary report. Regan J, Walshe M, Rommel N, McMahon BP., Dis Esophagus. 2013 Feb-Mar;26(2):117-23

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.