510(k) Summary
Page 1 of 7

JUL 17 2013

Date Prepared	28-Jun-13
Company	Crospon Ltd. Galway Business Park Dangan Galway, Ireland Tel – 011 [353] (91) 519882 Fax – 011 [353] (91) 519873
Official Contact:	John O'Dea PhD
Proprietary or Trade Name:	EndoFLIP® Catheters EF-325, EF-325L, EF-325N, BF-325, BF-325N EF-620
Common/Usual Name:	Gastrointestinal motility monitoring system
Classification / CFR:	FFX / CFR 876.1725 / Class 2
Device:	EndoFLIP® System and Catheter
Predicate Devices:	K092850 – Crospon – EndoFLIP® K102214 – Crospon – EndoFLIP® K120997 – Crospon – EndoFLIP® K983220 – Stryker – InfraVision™

Device Description:
The EndoFLIP® comprises a measuring system and a single use or reusable catheter to assist in measuring the lumen diameter at 16 points (EF family) or 8 points (BF family). The EndoFLIP® comprises a measuring system and catheter to assist in measuring lumens. In practice, the EndoFLIP® balloon catheter is attached to a syringe, pre-filled with a diluted saline solution, which is inserted into the syringe pump on the front of the EndoFLIP® system. The deflated balloon is inserted under direct laparoscopic visualization. Once the balloon has been correctly located, it is then inflated with the diluted saline solution to a user programmed volume.

Modifications of these devices vs. Predicates:

The following is a list of the changes to the EndoFLIP® catheters.

(1) Addition of a model designated as EF-325L that has a locating LED (colored red) positioned inside the wire lumen at the balloon midpoint. It is used in conjunction with the shaft markings to locate the balloon midpoint.

510(k) Summary
Page 2 of 7
28-Jun-13

(2) Extension of the shelf life from 1 year to 2 years for the following products:
   a. EF-325 and BF-325 family of catheters
   b. EF-620 family of catheters

Indications for Use:

- K092850 - The EndoFLIP® system is an endoscopically placed device 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 in a clinical setting.
- K102214 - EndoFLIP® EF-620 catheter is indicated for use in measuring the size of a gastric sleeve created during bariatric surgery. It is suitable for diameter measurements for 22 to 60 French sleeves.
- K120997 - The EndoFLIP® system is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity.

- Note: EndoFLIP is a measurement system. It is not intended to perform a diagnostic test. The EF-325L has a locating LED used in conjunction with the shaft markings to locate the balloon midpoint.

Patient Population: Patients undergoing bariatric surgery

Environment of Use: Hospitals and Surgery Centers

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

Predicate Device Comparison:

Table 1 compares the Catheters, while **Table 2** compares the EF-325L to the Predicate. One will note that the difference between EF-325 and BF-325 is that they are identical except in the number of electrodes and sensors.

The EF-325L is identical to the EF-325 other than the addition of a locating LED mounted on the shaft inside the balloon.

Note that the reference to "Nasal" is the tip design (deflective tip) and not to how the catheter is placed. All of these catheters are placed orally.

The catheters for use with the EndoFLIP® system are viewed as substantially equivalent to the predicate catheters because:

510(k) Summary
Page 3 of 7
28-Jun-13

Indications –
The indications for use are identical to the predicates.
Discussion – The indications for use are unchanged from the predicates, EndoFLIP® - K092850, K102214, and K120997.

Technology –
The technology, construction and design are unchanged.
Discussion – The technology is unchanged from the predicates, EndoFLIP® - K092850, K102214, and K120997.

Environment of Use –
The environments of use - Hospital and surgery centers – are identical.
Discussion – The environments of use are unchanged and identical to the predicates, EndoFLIP® - K092850, K102214, and K120997.

Patient Population –
The patient populations are identical and unchanged.

K092850 - Patients undergoing gastric band surgery and post-operative band adjustment
K102214 - Patients undergoing bariatric procedures
K120997 - Patients with esophageal disorders

Discussion – The patient population is unchanged and identical to the predicates, EndoFLIP® - K092850, K102214, and K120997.

Non-clinical Testing Summary -

We performed:

- Shelf-life Test

Packaging is identical to the predicate devices. The additional accelerated aging testing demonstrated that they performed to their specifications and thus are substantially equivalent to the predicate devices.

Materials –
The materials in contact with the patient are identical to predicate.
Discussion – The materials are unchanged and identical to the predicates, EndoFLIP® - K092850, K102214, and K120997.

510(k) Summary
Page 4 of 7
28-Jun-13

Table 1 – Comparison of Proposed Device vs. Predicate

	EndoFLIP® system with catheter K092850, K102214, K120997	**Proposed EndoFLIP® Catheters**
Indications for Use	K092850 The EndoFLIP® system is an endoscopically placed device 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 in a clinical setting. K102214 EndoFLIP® EF-620 catheter is indicated for use in measuring the size of a gastric sleeve created during bariatric surgery. It is suitable for diameter measurements for 22 to 60 French sleeves. K120997 The EndoFLIP® system is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity. Note: EndoFLIP® is a measurement system. It is not intended to perform a diagnostic test.	Identical, unchanged
Environments of use	Hospital and surgery centers	Identical, unchanged

510(k) Summary
Page 5 of 7
28-Jun-13

	EndoFLIP® system with catheter K092850, K102214, K120997	**Proposed EndoFLIP® Catheters**
Patient Population	K092850 – Patients undergoing gastric band surgery and post-operative band adjustment K102214 – Patients undergoing bariatric procedures K120997 – Patients with esophageal disorders	Identical, unchanged
Contraindications	The EndoFLIP® System is contraindicated where endoscopy is contraindicated.	Identical, unchanged
Prescription/OTC	Prescription use	Identical, unchanged
Principle of Operation	Provides an Estimated Diameter (D_{est}) of the balloon at 16 or 8 points along its length when inflated with saline solution. Records balloon pressure.	Identical, unchanged
Biocompatibility	All materials have passed biocompatibility tests in accordance with ISO 10993-1	Identical to K092850, unchanged
Compatibility With The Environment And Other Devices	Only operates with EndoFLIP® system	Identical, unchanged
Sterility	Accessories are supplied non-sterile, and are single patient use, disposable	Accessories are supplied non-sterile, and are single patient use, disposable
Performance	Range: 5 to 25 mm and 7 to 20 mm Resolution: 0.1 mm Accuracy: ± 1mm (at 95% confidence) rounded to nearest integer	Identical, unchanged

510(k) Summary
Page 6 of 7
28-Jun-13

Table 2 – Locating LED Comparison to Predicate

	Proposed EndoFLIP® EF-325L catheter	Predicate Stryker InfraVision™ K983220
Indications for Use	All of the EndoFLIP indications for use under K092850, K102214, and K120997 plus the new feature Transillumination is intended to help the surgeon with placement of EF-325L catheter	Specific indication for helping to locate or position devices Esophageal transilluminating dilation device with a reusable illumination source, and a combined single use disposable fiberoptic light guide, nasogastric tube and balloon dilation system. Intended to transilluminate and dilate the esophagus during fundoplication procedure. Transillumination is intended to help the surgeon placement of medical devices within body tissue.
Environments of use	Hospital and surgery centers	Identical
Patient Population	Identical to K092850, K102214, K120997	Similar
Contraindications	The EndoFLIP® System is contraindicated where endoscopy is contraindicated.	Not stated
Prescription/OTC	Prescription use	Prescription use
Principle of Operation	LED to assist with transillumination LED located inside balloon	Light source for transilluminating Separate light source
Materials used	The LED is located inside the catheter balloon and is isolated from the patient	N/A

The Locating LED feature does not alter the primary indications for use for the EF-325 catheter. It is to assist the user in locating the balloon mid-point. As the primary indications for use has not changed this feature can be as being substantially equivalent to the predicate because:

Indications –
The indications for use are identical to the predicate catheter and the predicate Stryker InfraVision™ system (K983220).

For the Locating LED feature
Transillumination is intended to help the surgeon with placement of EF-325L catheter
K983220 is indicated for helping to locate or position devices

Note: EndoFLIP® is a measurement system. It is not intended to perform a diagnostic test.

510(k) Summary
Page 7 of 7
28-Jun-13

Discussion – The indications for use are unchanged for the catheter from the predicates, EndoFLIP® - K092850, K102214, and K120997 and the Locating LED feature is similar to the predicate Stryker InfraVision (K983220).

Technology –
The technology, construction and design are unchanged. The addition of a low voltage LED with the pressure sensor inside the balloon does not alter the construction.
Discussion – The technology is unchanged from the predicates, EndoFLIP® - K092850, K102214, and K120997 and the addition of a LED for a light source is similar to the predicate Stryker InfraVision (K983220).

Materials –
The materials in contact with the patient are identical to predicate.
Discussion – The materials are unchanged and identical to the predicates, EndoFLIP® - K092850, K102214, and K120997.

Environment of Use –
The environments of use - Hospital and surgery centers – are identical.
Discussion – The environments of use are unchanged and identical to the predicates, EndoFLIP® - K092850, K102214, and K120997.

Patient Population –
The patient populations are identical and unchanged.

K092850
Patients undergoing gastric band surgery and post-operative band adjustment
K102214
Patients undergoing bariatric procedures
K120997
Patients with esophageal disorders

Discussion – The patient population is unchanged and identical to the predicates, EndoFLIP® - K092850, K102214, and K120997.

Non-clinical Testing Summary -

There was no additional non-clinical testing for the locating LED feature.

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.

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

July 17, 2013

Crospon Ltd.
% Paul Dryden
Regulatory Consultant
24301 Woodsage Dr.
Bonita Springs, FL 34134-2958

Re: K130906
Trade/Device Name: EndoFLIP® System with catheters (EF-325, EF325N, EF-325L, BF-325 BF-325N, EF-620)
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: June 28, 2013
Received: July 1, 2013

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 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,

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

Indications for Use Statement

510(k) Number: K130906

Device Name: EndoFLIP® System with catheters
- EF-325
- EF-325N
- EF-325L
- BF-325
- BF-325N
- EF-620

Indications for Use:

- The EndoFLIP® system is an endoscopically placed device 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 in a clinical setting.
- EndoFLIP® EF-620 catheter is indicated for use in measuring the size of a gastric sleeve created during bariatric surgery. It is suitable for diameter measurements for 22 to 60 French sleeves.
- The EndoFLIP® system is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity.

Note: EndoFLIP is a measurement system. It is not intended to perform a diagnostic test. The EF-325L has a locating LED used in conjunction with the shaft markings to locate the balloon midpoint.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.07.16 16:47:23 -04'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130906