

**510(k) Summary**

Page 1 of 3  
9-Dec-10

DEC 16 2010

**Company** Crospon Ltd.  
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Dangan  
Galway, Ireland

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**Official Contact:** John O’Dea PhD

**Proprietary or Trade Name:** EndoFLIP®

**Common/Usual Name:** Gastrointestinal motility monitoring system

**Classification / CFR:** FFX / CFR 876.1725

**Device:** EndoFLIP® System and Catheter

**Predicate Devices:** K092850 – Crospon – EndoFLIP®

**Device Description:**

The EndoFLIP® comprises a measuring system and a single use catheter to assist in measuring the gastric sleeve. 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 into the stomach by an anesthesiologist with placement being confirmed by the surgeon 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. The display estimates the gastric sleeve diameter at sixteen points along the balloon. The system also allows snapshots to be taken and compared to real-time images.

**Indications for Use:**

The EndoFLIP® EF-620 catheter is 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 60 French sleeves.

The EF-620 catheter is to be used only with the EndoFlip System.

**Patient Population:** Patients undergoing bariatric surgery

**Environment of Use:** Hospitals and Surgery Centers

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

510(k) Summary

Page 2 of 3

9-Dec-10

Device Attributes:

|   |  |
|---|--|
| <b>Design</b>   |  |
| <b>Principle of Operation</b>                               | Syringe pump device that targets an inflate volume within a balloon inserted into the lumen of an organ. Provides an Estimated Diameter ( $D_{est}$ ) of the balloon at 16 points along its length when inflated with custom conductive solution.                              |
|   | $D_{est}$ electrodes are located at 16 points along the catheter inside a balloon.   |
| <b>Energy Used And/Or Delivered</b>                         | No electrical energy is delivered into the patient   |
| <b>Human Factors</b>  | Specified for 20 to 40°C operating environment   |
|   | Touch screen user interface  |
|   | On screen keypad and external keypad interface provided  |
| <b>Data Recording</b>                                       | Data is saved internally and can be exported to a USB mass storage device or printed to an attached USB printer  |
| <b>Electrical Safety</b>                                    | IEC60601-1 2nd Ed. + Am.1 + Am.2   |
| <b>Mechanical Safety</b>                                    | Travel limits are detected by mechanical switches  |
|   | Syringe is automatically put in its home position at power on  |
|   | Maximum volume is set by the volume of solution in the syringe which is factory filled. This volume matches the balloon size on the catheter. The Balloon Inflate Volume cannot be set above the factory set syringe volume.   |
|   | The Deflate button is available after inflation has commenced. The syringe can be manually retracted at any time.  |
|   | Rigid syringe used to avoid potential volume errors  |
|   | Stepper motor driven lead screw is used to maintain accurate control over the syringe piston position. Piston movement resolution is 0.003175 mm (one step)  |
|   | No calibration required  |
| <b>Chemical Safety</b>                                      | Conductive solution inside balloon is diluted saline   |
| <b>Thermal Safety</b>                                       | Internal cooling fan with enclosure temperature monitoring. Alarm if temperature exceeds limits.   |
| <b>Biocompatibility</b>                                     | All materials have passed biocompatibility tests in accordance with ISO 10993-1  |
| <b>Compatibility With The Environment And Other Devices</b> | EndoFLIP operates with custom catheters only   |
| <b>Sterility</b>  | Accessories are supplied non-sterile and are single patient use  |
| <b>Performance</b>  | EndoFLIP ® passed the performance testing :<br>Estimated balloon diameter ( $D_{est}$ ) at 16 points in the balloon, displayed in numeric and graphical form<br>Range: 7 to 20 mm<br>Resolution: 0.1 mm<br>Accuracy: $\pm 1$ mm (at 95% confidence) rounded to nearest integer |

510(k) Summary  
Page 3 of 3  
9-Dec-10

**Substantial Equivalence:**

The EndoFLIP® system with EF-620 catheter is viewed as substantially equivalent to the predicate device because:

**Indications:**

Similar to predicate – K092850 – Crospon EndoFLIP® system with catheter measure the diameter of the stoma during gastric band procedures while the proposed indication of the EndoFLIP® EF-620 catheter is for use in measuring the size of a gastric sleeve created during bariatric surgery.

**Technology:**

Identical technology to predicate – K092850 – Crospon EndoFLIP® system with catheter

Both catheters can only be used with the predicate EndoFLIP® controller and the construction and materials of the new catheter are identical to the predicate.

**Materials:**

The materials in contact with the patient are identical to predicate device K092850 – Crospon EndoFLIP® system with catheter.

**Environment of Use:**

Identical to predicate – K092850 – Crospon EndoFLIP® system with catheter

**Patient Population:**

Identical to predicate – K092850 – Crospon EndoFLIP® system with catheter

**Comparative Performance and Specifications:**

We performed the appropriate bench testing to demonstrate that the new catheter in combination with the EndoFLIP® controller performs within the specifications of the predicate catheter with the EndoFLIP® controller.

Therefore one can find that the EndoFLIP® system with new catheter and the new indications for use are viewed as substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Crospon, Ltd.  
c/o Mr. Paul E. Dryden  
President and Regulatory Consultant  
ProMedic, Inc.  
24301 Woodsage Drive  
BONITA SPRINGS FL 34134-2958

DEC 16 2010

Re: K102214  
Trade/Device Name: EndoFLIP® System  
Regulation Number: 21 CFR §876.1725  
Regulation Name: Gastrointestinal motility and monitoring system  
Regulatory Class: II  
Product Code: FFX  
Dated: December 9, 2010  
Received: December 10, 2010

Dear Mr. 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,



Herbert P. Lerner, M.D., Director (Acting)  
Division of Reproductive, Gastro-Renal  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**510(k) Number:** K102214

**Device Name:** EndoFLIP® System

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The EF-620 catheter is to be used only with the EndoFlip System.

**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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K102214