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510(k) Summary
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30-Sep-11

K110531

Company	Crospon Ltd. Galway Business Park Dangan Galway, Ireland Tel – 011 [353] (91) 519882 Fax – 011 [353] (91) 519873
Official Contact:	John O'Dea, Ph.D.
Proprietary or Trade Name:	EndoFLIP® ECD EF-800
Common/Usual Name:	Endoscopic access overtube, gastroenterology-urology
Classification / CFR:	FED / CFR 876.1500
Device:	EndoFLIP® ECD EF-800
Predicate Devices:	US Endoscopy Enteroscopy Overtube (K100081) Smart Medical NaviAID BGE (K060923)

Device Description:
The EndoFLIP® ECD EF-800 External Channel Device (ECD) is an endoscopic accessory designed to provide an additional channel external to the endoscope for inserting, advancing, and removing endoscopic devices thereby preserving the working channel of the endoscope for other instruments.

Indications for Use:
The EndoFLIP® EF-800 is an external channel for an endoscope (9.0 – 12.2 mm in diameter) used to aid in the insertion, advancement, and removal of endoscopic devices during endoscopic procedures

Patient Population:	Patients undergoing endoscopic procedures
Environment of Use:	Hospitals, Sub-acute care institutions, Surgery Centers, doctor's offices where endoscopic procedures may be performed
Contraindications:	The ECD EF-800 is contraindicated where endoscopy is contraindicated.

Table of Comparison of Proposed Device vs. Predicate

	EndoFLIP® ECD EF-800	Smart Medical NaviAID BGE – K060923	US Endoscopy Enteroscopy Overtube - K100081
Attributes			
Indications for Use	The EndoFLIP® EF-800 is an external channel for an endoscope (9.0 to 12.2 mm in diameter) used to aid in the insertion advancement and removal of endoscopic devices during endoscopic procedures	An accessory to an endoscope and is intended to ensure complete positioning of a standard endoscope in the small intestine (i.e., an endoscope that is 10 -13 mm in diameter and is used for standard intestinal endoscopic visualization	Indicated for use to aid the insertion, advancement, and removal of appropriately sized endoscopes and endoscopic devices during diagnostic and therapeutic endoscopic procedures in the upper gastrointestinal tract, including the small intestine
Environments of use	Hospitals, Sub-acute care institutions, Surgery Centers, doctor's offices where endoscopic procedures may be performed	Hospitals, Sub-acute care institutions, Surgery Centers, doctor's offices where endoscopic procedures may be performed	Hospitals, Sub-acute care institutions, Surgery Centers, doctor's offices where endoscopic procedures may be performed
Patient Population	Patients undergoing endoscopic procedures	Patients undergoing endoscopic procedures	Patients undergoing endoscopic procedures
Contraindications	The ECD EF-800 is contraindicated where endoscopy is contraindicated.	The contraindications include those specific to the endoscopic procedure. Relative contraindications include: • Bowel obstruction • Concomitant Coumadin use • Diverticulitis Recent (within the last 3 months) coronary ischemia or CVA (stroke)	Not stated

	EndoFLIP® ECD EF-800	**Smart Medical NaviAID BGE – K060923**	**US Endoscopy Enteroscopy Overtube - K100081**
Functions	aid in the insertion advancement and removal of endoscopic accessories during endoscopic procedures.	aid the insertion, advancement, and removal of appropriately sized endoscopes and endoscopic devices	aid the insertion, advancement, and removal of appropriately sized endoscopes and endoscopic devices
Intraoperative use	Yes	Yes	Yes
Design			
Components			
Dual lumen shaft	Yes	Yes	No (single lumen)
Clip	Yes	Yes	No
Reinforcing wire	Yes	Yes	Yes
Tapered tip	Yes	Yes	Yes
Dual lumen			
Working	Yes	Yes	No
Endoscope	Yes	Yes	Yes Only a channel for endoscope
Dimensions (mm)			
Overall OD	20.3 mm	20.3 mm	19.5 mm (single lumen)
Working lumen ID	4.0 mm	4.0 mm	Not available
Endoscope lumen	Up to 13 mm	Up to 13 mm	16.7 mm
Overall length	718 mm	- -	- -
Working length	700 mm	1900 mm	500 mm
Sterility	Supplied non-sterile, and are single patient use, disposable	Supplied non-sterile, and are single patient use, disposable	Supplied non-sterile, and are single patient use, disposable
Performance Testing			
Shelf life	Age testing	Age testing	
Ability to slide over endoscope	Compatibility testing	Compatibility testing	Not available
Materials Biocompatibility	ISO 100993-1	ISO 10993-1	ISO 10993-1

Substantial Equivalence:
The EndoFLIP® ECD EF-800 is viewed as substantially equivalent to the predicate devices because:

Indications –
Equivalent to predicate – K100081 – US Endoscopy Enteroscopy overtube - indicated for use to aid the insertion, advancement, and removal of appropriately sized endoscopes and endoscopic devices during diagnostic and therapeutic endoscopic procedures in the upper gastrointestinal tract, including the small intestine.

Technology –
Similar to the predicate K060923, *without the balloon accessory*, Smart Medical – NaviAID BGE, a simple double lumen tube with a tapered tip at one end.

Materials –
The materials in contact were tested to ISO 109931 – Cytotoxicity, Irritation, and Sensitization

Environment of Use –
Identical to predicate – K060923 – Smart Medical NaviAID BGE - Hospitals, Sub-acute care institutions, Surgery Centers, doctor's offices where endoscopic procedures may be performed.

Patient Population –
Identical to predicate – K060923 – Smart Medical NaviAID BGE – Patients undergoing endoscopic procedures.

Comparative Performance and Specifications
We have performed age testing and compatibility with endoscopes similar to the tests performed by the predicate K060923 Smart Medical – NaviAID BGE.

The ECD EF-800 raises no new safety or efficacy concerns.

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.
% Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134

OCT - 6 2011

Re: K110531
Trade/Device Name: EndoFLIP® EF-800 External Channel Device
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: September 30, 2011
Received: October 4, 2011

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" (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,

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

Indications for Use Statement

510(k) Number: K110531

Device Name: EndoFLIP® EF-800 External Channel Device

Indications for Use:

The EndoFLIP® EF-800 is an external channel for an endoscope (9.0 to 12.2 mm in diameter) used to aid in the insertion, advancement, and removal of endoscopic devices during endoscopic procedures

The EndoFLIP® ECD is single patient use, disposable.

Environments of use – Hospitals, Sub-acute care institutions, Surgery Centers, doctor's offices where endoscopic procedures may be performed.

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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110531