February 15, 2019

Crospon Ltd
% Avishag Metzer
Regulatory Affairs Program Manager
Medtronic
2 Hacarmet St. New Industrial Park POB 258
Yoqneam 20962
ISRAEL

Re: K183072
Trade/Device Name: EndoFLIP System
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: Class II
Product Code: FFX
Dated: October 31, 2018
Received: November 5, 2018

Dear Avishag Metzer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183072

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 in adults and to measure pressure and dimensions in the esophagus, in patients from 5 years of age. 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.

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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510(k) Summary

I. SUBMITTER

Submitter Name and Address:	Crospon Ltd. (Medtronic) Galway Business Park Dangan Galway, Ireland
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Fax Number:	972 (73) 2501545
Establishment Registration Number:	3006897778
Date Prepared:	February 15, 2019

II. DEVICE

Device Trade Name(s):	Endoflip System
Device Common Name:	Gastrointestinal motility monitoring system
Classification:	Regulation: 21 CFR 876.1725 Gastrointestinal motility monitoring system Product Code: FFX: System, Gastrointestinal Motility (Electrical)

III. PREDICATE DEVICE(S)

Endoflip System K160725

IV. DEVICE DESCRIPTION

There is no change between the Predicate device (K160725) and Endoflip System.

The Endoflip System comprises a measuring system and a single use catheter to provide programmed balloon distensions.

The Endoflip System and catheter are identical to the predicate (K160725). The proposed modification to the Endoflip System is to add a specific age range that includes pediatrics to the indications for use statement.

V. 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 in adults and to measure pressure and dimensions in the esophagus, in patients from 5 years of age. 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.

VI. TECHNOLOGICAL CHARACHTERISTICS

There is no change in the technological characteristics of Endoflip System from the cleared predicate device (K160725).

VII. PERFORMANCE DATA

Clinical Evaluation

The body of evidence presented demonstrates the safety of the Endoflip device and highlights the potential clinical benefit of utilization in the pediatric population. Specifically, Endoflip was used in pediatric achalasia patients during myotomy surgeries enabling real time assessment of the adequacy of the myotomy. Other application described in the literature review involves the use of Endoflip in children with Eosinophilic esophagitis (EoE) to assess esophageal distensibility.

The proposed change in this submission does not raise new performance or safety issues.

VIII. CONCLUSION

Based on the clinical evaluation presented, the company believes that the Endoflip System and the predicate device are substantially equivalent and do not raise new issues of safety or effectiveness.