

510(k) Summary

OCT 26 2010

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

E-Cath Co. Ltd.
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510(k) Correspondent

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Date Prepared

September 3, 2010

Trade Name of Device

pHTip Disposable ISFET Catheter

Classification Name

Gastrointestinal motility monitoring system

510(k) Classification

FDA Class II – FFX – Regulation 876.1725

Predicate Devices

- K003580 Unisensor AG, UniTip Pressure Sensor Catheter
- K062222 Unisensor AG, High resolution GI catheter

Device Description and Intended Use

The pHTIP Disposable ISFET Catheter is a device used to measure pH activity in the stomach or esophagus by means of a probe with transducers, which is introduced through the nose into the gastrointestinal tract, and is intended especially for gastro esophageal testing for the severity of

acid reflux events. The device may include conductive rings for impedance studies, and may also include signal conditioning and amplifying equipment.

Clinical and Non-Clinical Testing

E-cath Co. Ltd did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical bench testing was performed in order to validate the design against the company's specified design requirements.

Biocompatibility

Biocompatibility testing was successfully completed on patient contacting materials according to standard ISO 10993-1.

EMC Compliance

EMC compliance of the pHTip Disposable ISFET Catheter was successfully completed according to standard IEC 60601-1-2 + A1.

Functional Testing

Functionality of the pHTip Disposable ISFET Catheter was validated under simulated use conditions.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

Substantial Equivalence

Based on the above, e-cath Co. Ltd. believes that the pHTip Disposable ISFET Catheter product is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

E-Cath Co., Ltd.
c/o Mr. Robert N. Clark
President & Senior Consultant
Medical Device Regulatory Advisors, Inc.
13605 West 7th Avenue
GOLDEN CO 80401

OCT 26 2010

Re: K102801
Trade/Device Name: pHTip™ Disposable ISFET Catheter
Regulation Number: 21 CFR §876:1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX and FFT
Dated: September 21, 2010
Received: September 27, 2010

Dear Mr. Clark:

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.

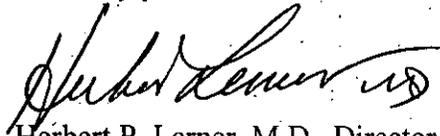
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Indications for Use

OCT 26 2010

510(k) Number (if known): K102801

Device Name: pHTip™ Disposable ISFET Catheter

Indications for Use:

The pHTip™ Disposable ISFET Catheter is a device used to measure intragastric and intraesophageal pH activity in the stomach or esophagus, by means of a flexible lead with ISFET pH electrodes that is introduced through the nose into the gastrointestinal tract. It is intended especially for gastro esophageal testing for the severity of acid reflux events. The device may include conductive rings for impedance studies, and may also include signal conditioning and amplifying equipment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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 K102801

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