K131131

Section 05_510(k) Summary

JUN 2 1 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: April 05, 2012

1. Company and Correspondent making the submission:

Name – IntroMedic Co., Ltd.
Address – Suite 1104, E&C Venture Dream Tower 6-Cha, 197-28 Guro-Dong, Guro-Gu, Seoul, 152-719 Korea
Telephone – +82-2-801-9300
Fax – +82-2-801-9330
Contact – JinYoung, Lee
Internet – http://www.intromedic.com

2. Device :

Proprietary name	: E.G. Scan™ II Esophagoscope System
Common Name	: Esophagoscope System
Classification Name	: Esophagoscope System

3. Predicate Device :

Manufacturer	: IntroMedic Co., Ltd,
Device	: E.G. Scan™ II Esophagoscope System
510(k) Number	: K120702

4. Classifications Names & Citations :

21CFR874.4710, EOX, Esophagoscope System, Class2

5. Description :

5.1 Introduction

E.G. Scan™ II Esophagoscope System and its accessories are used for diagnosis of patients. E.G. Scan™ II Probe takes pictures of the esophagus of human and sends

image data to E.G. Scan™ II Controller. E.G. Scan™ II Controller processes and converts image data and upload. E.G. View™ image displaying software displays the image for diagnosis.

The E.G Scan™ II Esophagoscope Probe is disposable.

5.2 General Technology

E.G. Scan™ II Esophagoscope system is a transnasal esophagoscope designed to capture images of the esophagus. Captured images are viewed via the E.G. View™ Software for diagnosis of diseases related to the esophagus.

6. Indication for use :

The E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

7. Comparison with predicate device :

The E.G. Scan™ II Esophagoscope System and predicate device are substantially equivalent in the areas of design, indication for use, technological characteristics, function, application and safety and effectiveness. This was determined by reviewing the information provided in the 510(k) in comparison to the content specified in the FDA guidance documents.

8. Safety, EMC and Performance Data :

The E.G. Scan™ II Esophagoscope System has the same device characteristics as the predicate device, E.G. Scan™ Esophagoscope System of IntroMedic Co., Ltd.; intended use, material, design and use concept are similar. The biocompatibility of the patient contact parts has been demonstrated through the cytotoxicity, sensitization and irritation testing by ISO 10993-1 Biological evaluation of medical devices. The E.G. Scan™ II Esophagoscope System conforms to IEC 60601-1 Medical electric equipment, Part 1: General requirements for safety, IEC 60601-2-18 Medical electrical equipment-Part 2: Particular requirements for the safety of endoscopic equipment and IEC 60601-1-2 Medical electric equipment, General requirements for safety collateral standard electromagnetic compatibility.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification IntroMedic Co., Ltd. concludes that The E.G. Scan™ II Esophagoscope System is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 21, 2013

IntroMedic Company, Limited
% Mr. Steve Kwon
Manager
IntroMedic USA Incorporated
3550 Wilshire Blvd. #738
Los Angeles, CA 90010

Re: K131131
Trade/Device Name: E.G. Scan™ II Esophagoscope System
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOX
Dated: April 22, 2013
Received: May 24, 2013

Dear Mr. Kwon:

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,

Deborah L. Falls -S

FDA

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K131131

Section 04.

Indications for Use

510(k) Number(if known):

Device Name: E.G. Scan™ II Esophagoscope System

Indications for Use:

E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 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)

Eric A. Mann -S