

JUN 20 2012

510(k) Submission – E.G. Scan™ II Esophagoscope System

510(k) Summary

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

Date: Dec. 06, 2011

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™ Esophagoscope System
510(k) Number : K111030

Manufacturer : Vision-Science, Inc.
Device : Modified Flexible Trans-Nasal Esophagoscope with Digital Video Processor and Disposable EndoSheath® System
510(k) Number : K072088

4. Classifications Names & Citations :

21CFR874.4710, EOX, Esophagoscope System, Class2

IntroMedic Co., Ltd.

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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

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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.

IntroMedic Co., Ltd.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

IntroMedic Company, Limited
% Mr. Marc M. Mouser
Underwriters Laboratories, Inc.
2600 NW Lake Road
Camas, WA 98607

JUN 20 2012

Re: K120702

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: II
Product Code: EOX
Dated: May 25, 2012
Received: June 1, 2012

Dear Mr. Mouser:

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,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological and Ear,

Nose and Throat Devices

Office of Device Evaluation Health

Center for Devices and Radiological Health

Enclosure

K120702

Indications for Use

510(k) Number(if known):

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

Indications for Use:

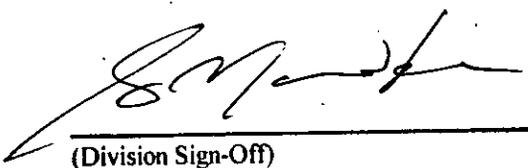
E.G. Scan™ II Esophagoscope System is intended for use in endoscopic access and examination of the larynx, esophagus and gastroesophageal junction.

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)

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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Prescription Use

(Per 21 CFR 801.109)

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