

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: Aug. 20, 2010

1. Company and Correspondent making the submission:

Name – IntroMedic Co., Ltd.

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Contact – JinYoung, Lee

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2. Device :

Proprietary name : E.G. Scan™ Esophagoscope System

Common Name : Esophagoscope System

Classification Name : Esophagoscope System

3. Predicate Device :

Manufacturer : Vision-Sciences, Inc.

Device : EndoSheath® Systems for use with VSI Flexible Scope

510(k) Number : K071903

Manufacturer : Vision-Science, Inc.

Device : Modified Flexible Trans-Nasal Esophagoscope with
Digital Video Processor and Disposable EndoSheath®
Systems

510(k) Number : K072088

Manufacturer : Boston Scientific Corporation
Device : Maxforce TTS Single-Use Balloon Dilator
510(k) Number : K061787

Manufacturer : Fujion, Inc.
Device : Fujinon Double Balloon Enteroscopy System
510(k) Number : K040048

4. Classifications Names & Citations :

21CFR874.4710, EOX, Esophagoscope System, Class2

5. Description :

5.1 Introduction

E.G. Scan™ Esophagoscope System and its accessories are used for diagnosis of patients. E.G. Scan™ Probe takes pictures of the esophagus of human and sends image data to E.G. Scan™ Controller. E.G. Scan™ Controller processes and converts image data and upload. E.G. View™ image displaying software displays the image for diagnosis.

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

5.2 General Technology

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

7. Comparison with predicate device :

IntroMedic Co., Ltd., believes that the Esophagoscope System (E.G. Scan) is substantially equivalent to EndoSheath® Systems for use with VSI Flexible TNE Scope of Vision-Sciences, Inc. and Modified Flexible Trans-Nasal Esophagoscope

with Digital Video Processor and Disposable EndoSheath® Systems of Vision-Sciences, Inc., Fujinon double balloon enteroscope of Fujinon, Inc..

Esophagus is always strongly contracted making it difficult to observe the lumen during the insertion. A balloon is needed in order to expand the size of the esophagus. Due to the small diameter of the probe and to avoid it leaning to one side in the esophagus, expansion of the balloon will allow the probe to be maintained in the center. As well as predicate device the Boston Scientific Corporation Maxforce TTS Single-Use Balloon Dilator is indicated for use in adults and adolescent populations to endoscopically dilate strictures of the esophagus.

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-2-18 and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). And Transportation and disinfection performance test were conducted. All test results were satisfactory.

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 is safe and effective and substantially equivalent to predicate devices as described herein.



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

Intramedic Co., LTD
c/o Mr. Marc Mouser
Engineering Leader, and Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
Camas, Washington 98607-9526

OCT 21 2011

Re: K111030

Trade/Device Name: Esophagoscope System
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOX
Dated: September 21, 2011
Received: October 3, 2011

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" (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,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K111 030

Indications for Use

510(k) Number(if known):

Device Name: E.G. Scan™ Esophagoscope System

Indications for Use:

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

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)

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

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Prescription Use
(Per 21 CFR 801.109)

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