12/7/99 K984168

SECTION II

510k SUMMARY OF SAFETY AND EFFECTIVENESS

The Summary of Safety and Effectiveness on the Barrett's Esophageal Cytology Device reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Procedure/Product Overview

The Barrett's Cytology Device is intended to collect cytologic samples from the esophageal mucosa without the aid of endoscopy for the purpose of cytologic analysis to determine the presence of abnormalities like Barrett's Esophagus. In the past the methods of obtaining cytologic samples from the gastrointestinal tract were limited to brush cytology completed under direct visualization methods via endoscopy. This method although proven has a high procedure cost associated with it. The Barrett's Cytology Device combines non endoscopic intubation catheter methods and cytology brush technology to provide a device that will lower the cost of surveillance for this patient population. The Barrett's Cytology Device is a catheter that is advanced into the esophagus much like a gastric lavage catheter. The catheter with the aid of common intubation techniques is further advanced into the stomach. The placement into the stomach is confirmed by the use of a distal inflatable balloon which is used to identify the lower esophageal sphincter (LES). Identification of the LES is required because the target sample location is typically the distal esophagus. Once the LES is identified an external slide disc on the catheter is used to mark the length of the patient's esophagus from the dental arches. At this time the balloon will be deflated and the catheter withdrawn away from the LES into the esophagus using the slide disc and catheter markings for distance reference as to how far back the catheter is to be withdrawn. When the catheter is withdrawn to the desired location to sample a cytology brush contained within the catheter is deployed out the distal end of the catheter and the cytologic brushing commences. Once the brushing of the esophagus is completed the brush is withdrawn back inside the catheter to contain the cell harvest within the

catheter lumen. The entire catheter is withdrawn from the patient and the cytology brush is again deployed to prepare microscopic slides for analysis.

Contraindications

The use of the Barrett's Cytology Device is contraindicated and is not appropriate in cases where the patients have or present with:

- Consideration of bleeding complications in patients with liver cirrhosis, esophageal varices, active gastroduodenal bleeding
- Consideration of the potential complications of esophageal or gastric bleeding and or perforation and aspiration digestive fluids into the lung.
- Consideration of stress associated with intubation procedures (gagging, discomfort) in patients with severe heart disease, hypertension, or pulmonary deficiencies.
- Reaction to topical anesthetics.
- Insertion may be complicated in patients with esophageal obstruction, acute laryngitis,or general debilitation of the patient due to other causes.
- Other contraindications as determined by physician.

Manufacturing Overview

U.S.E. will manufacture and test the product to performance specifications based on predicate and/or substantially equivalent devices.

U.S.E. quality system is based on the requirements of The FDA Quality System Regulations and it is also certified to ISO 9001 and EN46001 and markets devices under following the requirements of The European Medical Device Directive. The U.S.E. quality system methods and procedures are utilized to assure the product conformance to design specifications. The device design, development and validation will be implemented following relevant design control procedures.

Sterilization

This device will be offered in a sterile packaging configuration. The ethylene oxide gas process, packaging materials and methods will be subject to the validation requirements of the U.S.E. quality system.

Bibliography

Falk G, Chittajallu R, et al. Alimentary Tract - Surveillance of Patients with Barrett's Esophagus for Dysplasia and Cancer with Balloon Cytology. Gastroenterology. 1997;112:1787-1797

Falk G, Richter J, Reflux Disease and Barrett's Esophagus. Endoscopy. 1998; 30: 61-72

Roth M, Liu S, et al. Cytologic Detection of Esophageal Squamous Cell Carcinoma and Precursor Lesions Using Balloon and Sponge Samplers in Asymtomatic Adults in Linxian, China. Cancer. 1997; vol.80: 2047-2059

Rayhorn N, Intubation and Drainage. Gastroenterology Nursing A Core Curriculum.1998; Chapter 29:307-321

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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DEC - 7 1999

Mr. Dean Secrest
U.S. Endoscopy Group
5976 Heisley Road
Mentor, OH 44060

Re: K984168
Barrett's Esophageal Cytology Device
Dated: October 7, 1999
Received: October 12, 1999
Regulatory Class: II
21 CFR 876.1075/Procode: 78 FCF

Dear Mr. Secrest:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if Known K984168

Device Name: Barrett's Cytology Device

Indications for Use:

The Barrett's Cytology Device is intended to collect cytologic samples from the esophageal mucosa without the aid of endoscopy for the purpose of cytologic analysis to determine the presence of abnormalities like Barrett's Esophagus.

(please DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____ (Per 21 CFR 801.109)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984168/S002