DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 1, 2016

EndoChoice, Inc.
Daniel Hoefer
Regulatory Affairs Manager
11810 Wills Road
Alpharetta, GA 30009

Re: K160275
Trade/Device Name: Fuse® Endoscopy System with FuseBox® Processor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Codes: PEA, FDF, FDS
Dated: June 30, 2016
Received: July 1, 2016

Dear Mr. Hoefer:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160275

Device Name
Fuse® Endoscopy System with FuseBox® Processor

Indications for Use *(Describe)*

Fuse Colonoscopy System

The Fuse Colonoscope with FuseBox Processor is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The system consists of EndoChoice camera heads, endoscopes, video system, light source and other ancillary equipment. Fuse Colonoscopes, in conjunction with the FuseBox® processor, are indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients. The system includes Lumos, a digital post processing image enhancement technology. Lumos is intended to be used as an optional adjunct following white light endoscopy and is not intended to replace histopathological sampling as a means of diagnosis.

Fuse 1G Gastroscopy System

The Fuse 1G Gastroscope with FuseBox Processor is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The system consists of EndoChoice camera heads, endoscopes, video system, light source and other ancillary equipment. The Fuse 1G Gastroscope, in conjunction with the FuseBox processor, is indicated for use within the upper digestive tract (including the esophagus, stomach and duodenum). The system includes Lumos, a digital post processing image enhancement technology. Lumos is intended to be used as an optional adjunct following white light endoscopy and is not intended to replace histopathological sampling as a means of diagnosis.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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This traditional 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92

510K Summary - K160275

I. Applicant information:

EndoChoice Inc.
11810 Wills Road
Alpharetta, GA 30009
Establishment Registration: 3007591333

Contact Person: Daniel Hoefer, EndoChoice Inc. USA
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Fax: 678-878-3373
E-mail: daniel.hoefer@endochoice.com
Date Prepared: July 29, 2016

II. Device information:

Trade Name: Fuse® Endoscopy System with FuseBox® Processor
Common Name: Endoscope and accessories, flexible/rigid
Classification: Class II per 21 CFR 876.1500
Product Code:

Classification Name	CFR Section	Product Codes
Endoscope, accessories, image post processing for color enhancement	21 CFR 876.1500	PEA
Colonoscope And Accessories, Flexible/Rigid		FDF
Gastroscope And Accessories, Flexible/Rigid		FDS

III. Predicate Device:

Fuse Gastroscopy System K152182 (EndoChoice Inc.)
Fuse Colonoscopy System K141598 (EndoChoice Inc.)

No reference devices were used in this submission.

IV. Device Description:

The Fuse Endoscopy System is a GI platform indicated for diagnostic visualization and therapeutic intervention of the digestive tract. The system labeled for healthcare facilities/hospitals enables physicians to view a high-resolution wide field of view. The FuseBox is responsible for image processing, transferring video signals from the endoscope, pneumatic control, and outputting high definition (HD 1080p) video signal. The current FuseBox version, unlike the version used with the two predicate devices, includes image post processing algorithm as an adjunct tool to white light visualization.

The feature provides real-time enhancement and will be used as an adjunctive tool, to supplement the white light endoscopic examination. The new feature may enhance appearance of surface vessels, visualization of the mucosal surface texture and visibility of borders of areas of interest when present.

V. Indication for Use:

Fuse Colonoscopy System

The Fuse Colonoscope with FuseBox Processor is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The system consists of EndoChoice camera heads, endoscopes, video system, light source and other ancillary equipment. Fuse Colonoscopes, in conjunction with the FuseBox® processor, are indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients. The system includes *Lumos*, a digital post processing image enhancement technology. *Lumos* is intended to be used as an optional adjunct following white light endoscopy and is not intended to replace histopathological sampling as a means of diagnosis.

Fuse 1G Gastroscopy System

The Fuse 1G Gastroscope with FuseBox Processor is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The system consists of EndoChoice camera heads, endoscopes, video system, light source and other ancillary equipment. The Fuse 1G Gastroscope, in conjunction with the FuseBox processor, is indicated for use within the upper digestive tract (including the esophagus, stomach and duodenum). The system includes *Lumos*, a digital post processing image enhancement technology. *Lumos* is intended to be used as an optional adjunct following white light endoscopy and is not intended to replace histopathological sampling as a means of diagnosis.

VI. Comparison of Characteristics and intended use

Table 5.1

Category	**Predicate: Fuse Colonoscopy System K141598 (EndoChoice Inc.)**	**Predicate: Fuse Gastroscopy System K152182 (EndoChoice Inc.)**	**Proposed device: Fuse System with FuseBox Processor**
Performance Characteristics			
Intended use	Diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The system consists of EndoChoice camera heads, endoscopes, video system, light source and other ancillary equipment.	Diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The system consists of EndoChoice camera heads, endoscopes, video system, light source and other ancillary equipment.	Same as predicates
Mode of Operation	The Processor relays the image from the endoscope to a video monitor	The Processor relays the image from the endoscope to a video monitor	Same as predicates
User Interface	Manual and GUI	Manual and GUI	Same as predicates
Field of View	300° horizontal 330° diagonal	210° horizontal 245° diagonal	Same as predicates (combined)
Depth of Field [mm]	3-100	3-100	Same as predicates
FuseBox Characteristics			
Digital Output (Display)	3 channels DVI	3 channels DVI	Same as predicates
Analog Video Output (Image Management System)	3 X S Video	3 X S Video	Same as predicates
Imaging algorithm for enhancement feature	None	None	**Lumos Adaptive Matrix Imaging*™
Enhancement mechanism	None	None	Image processing of local contrast enhancement of intensity and tone resulting in modification of the combination of RGB components for each pixel. Fuse system enhancement mechanism allows retaining the neutral color of the tissue for human observer.
Number of enhancement	None	None	2 graduating enhancement

Category	Predicate: Fuse Colonoscopy System K141598 (EndoChoice Inc.)	Predicate: Fuse Gastroscopy System K152182 (EndoChoice Inc.)	Proposed device: Fuse System with FuseBox Processor
levels			modes for each intended use: Low gastro, high gastro Low colono, high colono
Adjustable image settings (GUI)	Red, blue, Brightness	Red, blue, Brightness, Sharpness (default level only)	***Adjustable sharpness levels added*
LED Intensity control	Yes	Yes	Same as predicates
Zoom	Yes	Yes	Same as predicates
Freeze/Release	Yes	Yes	Same as predicates
Flash Mode	Yes	Yes	Same as predicates
Control signals	White balance A/W pump control LED control	White balance A/W pump control LED control	Same as predicates
Illumination	Integral LED illumination	Integral LED illumination	Same as predicates
CCD type	Color	Color	Same as predicates
Electrical class	Class I , Type BF	Class I , Type BF	Same as predicates
Umbilical cord	90 degree orientation available	90 degree orientation available	Same as predicates
Locking lever	Yes	Yes	Same as predicates

*The main difference is the addition of *Lumos Adaptive Matrix Imaging*) feature. The feature is used as an adjunct to the white light image for visualization of the digestive tract.
** Addition of manually adjustable sharpness levels in order to support user preference, the low level is similar to default sharpness level of predicate K152182

VII. Performance testing:

The following testing has been performed to demonstrate that the design outputs of the modified version meet the design input requirements. The tests were performed within EndoChoice's laboratory or by accredited third parties.
In house Bench tests functional/software testing:

- Image quality testing (spatial resolution, field of view, depth of field, uniformity, geometric distortion, noise properties and color performance)
- Clinical Survey on videos with the Lumos compared to white light

All test results demonstrated that the device is safe and effective in comparison with the predicate device.

Substantial Equivalence:

The data presented above demonstrate that:

a. The Fuse Endoscopy System with FuseBox Processor and the predicate devices, have

the same intended use.

b. The Fuse Endoscopy System with FuseBox Processor and the predicate devices have similar indications, the *Lumos Adaptive Matrix Imaging* feature is an addition to the indication for use
c. Fuse Endoscopy System with FuseBox Processor and the predicate devices have similar technological characteristics
d. The Fuse Endoscopy System with FuseBox Processor and the predicate devices have same performance characteristics of white light. The *Lumos Adaptive Matrix Imaging*) provides an additional feature adjunct to white light endoscopy.

VIII. **Conclusion**:

Based on the results of verification, validation, and performance testing, the impact of the above differences is insignificant in terms of the device safety and effectiveness for the device's intended use. The modified device performs as well as intended in all testing performed.
It is the opinion of EndoChoice Inc., that the modified version of the Fuse Endoscopy System is substantially equivalent to the predicate devices in terms of safety and effectiveness.