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

December 10, 2015

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

Re: K152182
Trade/Device Name: Fuse® Gastroscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS
Dated: November 11, 2015
Received: November 13, 2015

Dear Daniel 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" (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 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 yours,

Herbert P. Lerner -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)*
K152182

Device Name
Fuse® Gastroscopy System

Indications for Use *(Describe)*
The Fuse Gastroscopy System is intended for diagnostic visualization of the digestive tract.
The system also provides access for therapeutic interventions using standard endoscopy tools. The Fuse Gastroscopy System is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).
The Fuse Gastroscopy System consists of camera heads, endoscopes, video system, light source and other ancillary equipment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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This special 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

Applicant information:

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

Contact Person:	Daniel Hoefer, EndoChoice Inc. USA
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Date Prepared: August 4, 2015

Device information:

Trade Name:	Fuse® Gastroscopy System
Common Name:	Colonoscope and accessories, flexible/rigid
Classification:	Class II per 21 CFR 876.1500
Product Code:	FDS
Predicate Device:	Fuse PeerScope HG (K131422)
Reason for Submission:	Modification of an existing device

Intended use and indications for use:

The Fuse Gastroscopy System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The Fuse Gastroscopy System is indicated for use within the upper digestive tract (including the esophagus, stomach, and duodenum).
The Fuse Gastroscopy System consists of camera heads, endoscopes, video system, light source and other ancillary equipment.

Device Description:

The Fuse Gastroscopy System is a GI platform indicated for diagnostic visualization and therapeutic intervention of the upper digestive tract. The purpose of this submission is to propose new biopsy channel supplier and also to present several design changes that enhance device usability and robustness. The indications for use, fundamental technology and operation principals of the legally marketed device were not changed. The system labeled for healthcare facilities/hospitals enables physicians to view a high-resolution wide field of view of up to 245° (measured diagonally), or 210° (measured horizontally)

Characteristics Comparison:

The modified version of the Fuse Gastroscopy System incorporates the following additional features compared to the unmodified version of the PeerScope HG (Branded Fuse Gastroscopy System) (K131422) which is the predicate:

Table 5.1

Category	PeerScope HG (K131422) unmodified version	Fuse Gastroscopy System modified version	Impact of modification/change on device performance
New supplier for working channel	Teflon PTFE (by Advanced Power Group)	PTFE (by EDC)	No impact on device performance, this material is similar and used by medical industry. Biocompatibility and reprocessing testing were repeated to ensure device safety.
Angulation Knob Brake	U/D	U/D R/L	Both designs utilize industry-accepted standard for handle brake.
Umbilical cord plug/socket	Discrete	Integrated	Both designs utilize Industry-accepted standard for usability.
Locking lever	NA	Added to FuseBox	This feature was added as part of user experience improvements and has no effect on device safety or performance
90 degree orientation of umbilical cord	NA	Added to device scope	This feature was added for AER compatibility as part of user experience improvements and has no effect on device safety or performance
Post procedure reprocessing method	Manual	Manual and Automated	Both designs utilize Industry-accepted standard for reprocessing compliance. Manual methods were updated and validated to adapt accepted standard care methods

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, performance, and software testing
- Laboratory Safety / EMC compatibility
- Laboratory Biocompatibility testing
- Laboratory Reprocessing testing

All test results passed, demonstrating that the device is safe and effective in comparison with the predicate device.

The following standards were used / relied upon for testing:

AAMI / ANSI ES 60601-1:2005/(R) 2012 and C1:2009/(R) 2012
AAMI / ANSI ES60601-1:2005/A1:2012
IEC 60601-1-2: 2007-03
IEC 60601-2-18 2009-08
IEC 62304:2006
ISO 10993:2009 Part #1
ISO 10993:2009 Part #5
ISO 10993:2010 Part #10
ISO 10993:2012 Part #12
ISO 8600-1:2013
ISO 8600-3:1997
ISO 8600-4:2014
ISO 8600-6:2005
ASTM E 1837- 96 (reapproved 2007)

Substantial Equivalence:

The data presented above demonstrate that:

a. The modified version of the Fuse Gastroscopy System and the unmodified version PeerScope HG (K131422), the legally marketed predicate, have the same intended use and indications for use in the upper digestive tract.
b. The modified version of the Fuse Gastroscopy System uses the same technological characteristics as the predicate.
c. The modified version contains similar materials, and similar reprocessing techniques, except for working channel. This was tested for reprocessing and biocompatibility.

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 the predicate in all testing performed. It is the opinion of EndoChoice Inc., that the modified version of the Fuse Gastroscopy System is substantially equivalent to the predicate device in terms of safety and effectiveness.