DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 30, 2014

EndoChoice, Inc.
Tamar Fuerst
RA Manager
11810 Wills Road
Alpharetta, GA 30009

Re: K141598
Trade/Device Name: Fuse® Colonoscopy System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: September 3, 2014
Received: September 5, 2014

Dear Tamar Fuerst,

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,

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)*
K141598

Device Name
Fuse® Colonoscopy System

Indications for Use *(Describe)*
The Fuse® Colonoscopy System is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. 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 Fuse® Colonoscopy System consists of EndoChoice 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: 300759133

Contact Person: Tamar Fuerst, EndoChoice Innovation Center Ltd.
Phone: (+972) 4-626-7321
Fax: (+972) 4-626-0205
E-mail: tamar.fuerst@endochoice.com

Date Prepared: June 2nd, 2014

Device information:

Trade Name:	Fuse® Colonoscopy System
Common Name:	Colonoscope and accessories, flexible/rigid
Classification Name:	Endoscope and accessories
Classification:	Class II per 21 CFR 876.1500
Product Code:	FDF
Predicate Device:	Fuse™ 1C System (K132839)
Reason for Submission:	Modification of an existing device.

Intended use and indications for use:

The Fuse® Colonoscopy system is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. 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 Fuse® Colonoscopy system consists of EndoChoice camera heads, endoscopes, video system, light source and other ancillary equipment.

Device Description:

The Fuse® Colonoscopy System is a GI platform indicated for diagnostic visualization and therapeutic intervention of the lower digestive tract in adult patients. The purpose of this submission is to expand the product sizes available for the legally marketed unmodified version Fuse 1C System (K132839) by adding two additional lengths: 133cm and 150cm to the current 168cm Fuse 1C colonoscope.

This 510(k) submission also presents several design changes to the system. 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 330°.

Characteristics Comparison:

The modified version of the Fuse 1C System incorporates the following additional features compared to the unmodified version of the Fuse 1C System (K132839) which is the predicate:

Table 5.1

Category	Fuse™ 1C System (K132839) unmodified version	Fuse® 1C System modified version	Impact of modification/change on device performance
Colonoscope working length	Standard (168 cm)	Standard (168cm) and Shortened (133cm, 150cm)	Both designs utilize industry-accepted standard for working lengths
Angulation Knob Brake	U/D	U/D R/L	Both designs utilize industry-accepted standard for handle brake.
Umbilical cord plug	Discrete	Integrated	Both designs utilize Industry-accepted standard for usability.
Umbilical cord socket			
Post procedure reprocessing method	Manual	Manual and Automated	Both designs utilize Industry-accepted standard for reprocessing compliance.
Insertion tube coating	TPU	TPU	Both materials are a TPU, having similar properties.
Adhesives	Epoxy resin	Epoxy resin	Both materials are epoxy resins, having similar properties.
Software	Version 1.0	Version 1.1.7	Enhanced features.

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 and by accredited third parties.

- In house Benchtop functional, performance, and software testing
- Laboratory Safety / EMC compatibility re-testing.
- Laboratory AER validation
- Laboratory Biocompatibility 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
IEC 60601-2-18 Edition 3.0 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 third edition 2013
ISO 8600-3 First edition 1997-07-01
ISO 8600-4 First edition 1997-07-01
ISO 8600-6 First edition 2005-03-15
ASTM E 1837- 96 (reapproved 2007)

Substantial Equivalence:

The data presented above demonstrate that:

a. The modified version of the Fuse 1C System and the unmodified version Fuse 1C System (K132839), the legally marketed predicate, have the same intended use and indications for use in the lower digestive tract.
b. The modified version of the Fuse 1C System uses the same technological characteristics as the predicate. It includes additional colonoscope insertion tube sizes.
c. The modified version contains similar materials, and similar reprocessing techniques.

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 1C System is substantially equivalent to the predicate device in terms of safety and effectiveness.