DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 8, 2016

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

Re: K151475
Trade/Device Name: Endochoice Select Injection Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: January 6, 2016
Received: January 8, 2016

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,

Benjamin R. Fisher -S

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)*
K151475

Device Name
EndoChoice Select Injection Needle

Indications for Use *(Describe)*

The EndoChoice Select injection needle is intended for endoscopic injection into the gastrointestinal mucosa.

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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Special 510(k) Summary

1. Company Identification

EndoChoice, Inc.
11810 Wills Road
Alpharetta, GA 30009
Telephone (678) 708 4743
FAX (678) 878 3373
Establishment Registration: 3007591333

2. Contact Person

Daniel Hoefer
Regulatory Affairs Manager

3. Device Name

Trade name:	EndoChoice Select Injection Needle
Common/Usual Name:	Injection Needle

4. Device Classification

Common Name:	Injection Needle
Classification:	Endoscope accessories, 21CFR 876.1500
Product Code:	FBK
Committee:	Gastroenterology/Urology

5. Indications for Use

The EndoChoice Select injection needle is intended for endoscopic injection into the gastrointestinal mucosa.

6. Device Description

The EndoChoice Select Injection Needle mainly consists of a cap, needle, boosting tube, and positioning ring, all made of 304 stainless steel. It also contains an outer tube and nut made of PTFE. The spring and spring tube are made of 302 stainless steel. The shell and injection handle are made of ABS. The bushing is made of TPE (SBS), the inner tube is made of nylon, and the color band indicator is made of CNBR.

The products are intended for single use; an individual device is packed in a sealed pouch following ETO sterilization. The device is used for local injection via endoscope, with the average contact time of the products and the mucosa of the human digestive tract of less than1 hour.

7. Substantial Equivalence

7.1 Predicate devices

The modified EndoChoice Select Injection needle is substantially equivalent to the predicate devices, EndoChoice Injection Needle (K132065) manufactured by EndoChoice, Inc. The intended use, design and materials and labeling are all substantially equivalent.

The predicate device as described in K132065 included 2 catheter configurations. This modification applies only to the version utilizing a Teflon sheath and does not apply to the catheter design, which incorporates a stainless steel spring. This submission has been prepared to address a change, in which a new patient contacting material has been introduced, as identified in the *Needle select design assembly* attached.

7.2 Intended Use

The indications for use of the modified EndoChoice Select Injection Needle is unchanged from the predicate device, the EndoChoice Injection Needle (K132065) manufactured by EndoChoice. In each case, the injection needle is intended for endoscopic injection into tissues of the digestive system.

7.3 Technical Characteristics

The injection needle is available in multiple sizes and two styles. The needle gauge sizes are available in 22 gauge and 25 gauge needles. Two styles of sheaths are available; one style is a metal stainless steel spring sheath and the other is a Teflon sheath. The modified EndoChoice Select Injection Needle only applies to the Teflon sheath configuration.

7.4 Performance Characteristics

The steps for operator use of each of the devices are equivalent. The instructions for use describe how to use the device with a standard endoscope, which is unchanged from the predicate.

7.5 Substantial Equivalence Table

Substantial Equivalence Comparison			
	EndoChoice Injection Needle Predicate (K132065)	Modified EndoChoice Select Injection Needle	Substantial equivalence
Manufacturer	EndoChoice, Inc.	EndoChoice, Inc.	Equivalent
Compatible with currently available endoscopes	Yes	Yes	Equivalent
Supplied Sterile	Yes	Yes	Equivalent
Sheath diameter	2.3mm	2.3mm	Equivalent
Needle size	22-25 gauge	22-25 gauge	Equivalent
Outer Tubing	Thermoplastic polymer-Teflon	Thermoplastic polymer-Teflon	Equivalent
Length	240 cm	240 cm	Equivalent
Needle extension length	5 mm	5 mm	Equivalent
Indications for use	The EndoChoice Select Injection Needle is intended for endoscopic injection into the gastrointestinal mucosa.	The EndoChoice Select Injection Needle is intended for endoscopic injection into tissues of the digestive system.	Equivalent
Packaging	Single-use EO sterilized Tyvek pouch with one device per pouch.	Single-use EO sterilized Tyvek pouch with one device per pouch.	Equivalent

8. Non-Clinical testing

Biocompatibility, accelerated aging and sterilization testing is unchanged from the predicate Injection Needle, which demonstrates that this device is safe and effective for use. Testing was based on a formal risk analysis. Biocompatibility testing was performed for the new patient contacting material of the modified device.

All test results passed, demonstrating that the safety and efficacy is equivalent to the predicate device.

9. Conclusion

The EndoChoice Select Injection Needle is substantially equivalent to the predicate device listed above. It is the same or equivalent in terms of design, intended use, materials and labeling.