This 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.

Submitter Name and Address:	EndoChoice, Inc. 11810 Wills Rd Alpharetta, GA 30009
Contact Person:	Theron Gober Director, Quality and Regulatory
Phone Number:	678-534-6021
Fax Number:	770-962-6981
Establishment Registration Number:	300759133
Date Prepared:	December 10, 2013
Device Trade Name(s):	Injection Needle
Device Common Name:	Injection Needle
Classification Name:	FBK
Predicate Device(s):	*Medi-Globe Injectra injection needle (K061222)*

JAN 17 2014

General Device Description:	The *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), and the inner tube is made of nylon. 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 product and the mucosa of the human digestive tract of less than 1 hour.
Intended Use:	The injection needle is intended for endoscopic injection into the gastrointestinal mucosa.
Technological Characteristics:	The injection needle is available in two sizes and two styles. The two sizes relate to the needle gauge. The sizes are 19 gauge and 22 gauge. Two styles of sheaths are available. The two styles of the device are identical with the exception of the addition of a stainless steel spring in one style. This stainless steel spring is present in the inner catheter of the *EndoChoice Injection Needle*, whereas it is not present in the predicate. The design is intended to ensure repeatable needle deployment in a tortuous path by maintaining a columnar deployment channel.
Testing Performed:	Biocompatibility, accelerated aging, performance, and sterilization validation testing was performed on the injection needle that demonstrated that this device is safe and effective for use. Testing was based on a formal risk analysis. The following table shows a summary substantial equivalence of the *EndoChoice Injection Needle* and the chosen predicate, indicating no additional safety risks arise in the new device based on similarities in materials, intended use, and function of the *EndoChoice Injection Needle* in comparison to the predicate device.

	EndoChoice Injection Needle:	Medi-Globe Injectra Injection Needle:	Substantial Equivalence:
Compatible with currently available endoscopes:	Yes	Yes	Equivalent
Supplied Sterile	Yes	Yes	Equivalent
Sheath diameter:	2.3 mm	2.5 mm	Similar
Needle size:	22 – 25 gauge	22 – 25 gauge	Similar
Outer tubing:	Thermoplastic polymer – PTFE	Thermoplastic Polymer	Similar
Length:	240 cm.	230 cm.	Similar
Needle Length:	5 mm	4 mm	Similar
Indications for use:	The *EndoChoice Injection Needle* is intended for endoscopic injection into the gastrointestinal mucosa.	The *Medi-Globe Injectra Injection Needle* is used in conjunction with various legally marked, FDA registered flexible endoscopes. The *Injectra* Needle is used for endoscopic injection of solutions into tissues of the digestive system and injection of saline as a procedural aid in endoscopic polypectomy procedures.	Similar
Packaging:	Single-use EO sterilized tyvek pouch with one device per pouch.	Single-use EO sterilized steam sealed pouch with one device per pouch.	Similar

Conclusion:	Based on the technological characteristics and overall performance of the devices, EndoChoice, Inc. believes that the *Injection Needle* and the predicate device selected are substantially equivalent. While the intended uses are slightly different, both devices are intended to be used in the same body regions during endoscopic procedures for injection of fluids. Therefore, this difference is minor, and does not raise new issues of safety or effectiveness.

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

January 17, 2014

EndoChoice, Inc.
Theron Gober
Director, Quality and Regulatory
11810 Wills Road
Alpharetta, GA 30009

Re: K132065
Trade/Device Name: Injection Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: December 13, 2013
Received: December 17, 2013

Dear Theron Gober,

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,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K132065

Device Name

Injection Needle

Indications for Use *(Describe)*

The 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)

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)*

Benjamin R. Fisher -S
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