K111895 APR 27 2012

510(k) SUMMARY

Submitted By: Marge Walls-Walker, Senior Regulatory Specialist: Engineering
Wilson-Cook Medical, Inc./Cook Endoscopy
4900 Bethania Station Road
(336) 744-0157
June 30, 2011

Name of Device

Trade Name:	EchoTip® Ultra Fiducial Needle
Common/Usual Name:	Implantable clip
Proposed Classification Name(s):	Marker, Radiographic, Implantable 21CFR 878.4300, NEU, Class II, and Kit, Needle, Biopsy 21 CFR 876.1075, FCG, Class II

Predicate Devices

BiomarC® Preloaded Tissue Marker Device, 510(k) No. K042296, cleared September 20, 2004

EchoTip® Ultra Ultrasound Needle, 510(k) No. K083330, cleared February 6, 2009

Intended Use

This device is intended to implant fiducials under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.

Device Description

The EchoTip® Ultra Fiducial Needle is composed of a delivery system (i.e., needle, sheath, handle, and stylet) with four pure gold fiducials preloaded and secured within a laser-cut track in the needle. The needle is dimpled to enhance its echogenicity, allowing the user to target tissues using endoscopic ultrasound guidance. The needle stylet is advanced to deploy the fiducials. Once deployed, the fiducials are permanent implants that serve as radiopaque reference points for future therapeutic procedures.

Substantial Equivalence

The EchoTip® Ultra Fiducial Needle is substantially equivalent to the BiomarC® Preloaded Tissue Marker Device (510(k) No. K042296). Both devices are composed of fiducials (i.e., tissue markers) preloaded within a delivery system. Once deployed, the radiopaque fiducials permanently mark soft tissue for therapeutic procedures.

The delivery system (i.e., needle, sheath, handle, and stylet) of EchoTip® Ultra Fiducial Needle is substantially equivalent to the EchoTip® Ultra Ultrasound Needle (510(k) No. K083330). Both are dimpled, endoscopic ultrasound needles that may be used to inject materials into tissues. The delivery system of the EchoTip® Ultra Fiducial Needle is a modified version of the EchoTip® Ultra Ultrasound Needle. Specifically, a laser cut track with notch has been added to the needle to secure the fiducials and a thumb ring has been added to the stylet hub to improve the ergonomics of fiducial deployment.

Discussion of Tests and Test Results

Cook conducted verification and validation testing establishing that design outputs met the design inputs. No toxicological concerns for pure gold implanted fiducials were identified by a Risk Assessment inclusive of exhaustive extraction under polar and non-polar conditions with accompanying chemical characterizations as well as the following biocompatibility tests: cytotoxicity, irritation sensitization and implantation. Additionally, simulated use demonstrated that the device could be used effectively without detachment or breakage, the fiducials were visible under ultrasound and common radiographic imaging techniques, and the fiducials are MR Conditional, as defined by ASTM F2503-08, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment* and the FDA guidance, *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment.*

Conclusions Drawn from the Tests

Outcomes from the evaluation of the EchoTip® Ultra Fiducial Needle provide evidence of its ability to mark soft tissues for future therapeutic procedures via endoscopic ultrasound placement and establish that it is substantially equivalent to the predicate devices in terms of intended use, biological safety and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

APR 2 7 2012

Ms. Marge Walls-Walker
Senior Regulatory Specialist: Engineering
Wilson-Cook Medical, Inc. /Cook Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K111895
Trade/Device Name: EchoTip® Ultra Fiducial Needle
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU and FCG
Dated: April 19, 2012
Received: April 23, 2012

Dear Ms. Walls-Walker:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

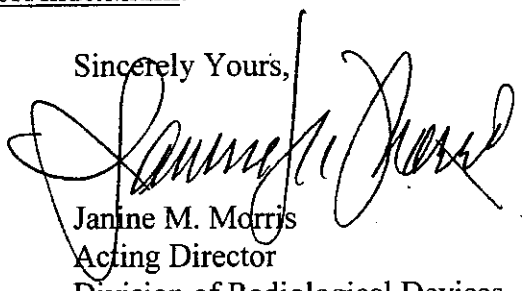
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K111895

Device Name: EchoTip® Ultra Fiducial Needle

Indications for Use: Intended to implant fiducials under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.

Prescription Use __XX___ AND/OR Over-the-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CRF 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111895