JUN 2 0 2014

K141356
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510(k) SUMMARY

Submitted By: Marge Walls-Walker, Senior Regulatory Specialist
Wilson-Cook Medical, Inc. /Cook Endoscopy
4900 Bethania Station Road
Winston-Salem, NC 27105
(336) 744-0157 x-6290
May 12, 2014

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

EchoTip® Ultra Fiducial Needle, k 111895, cleared 4.27.2012

Intended Use

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

Device Description

The modified EchoTip® Ultra Fiducial Needle is generally identical to the cleared predicate device. The modified device is also 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. The Intended Use and Indications for Use are identical in the modified device as is the fundamental operating principle. Modifications to this iteration of the device include minor dimensional, geometric and tolerance adjustments.

Substantial Equivalence

The EchoTip® Ultra Fiducial Needle, subject of this Special 510(k) is substantially equivalent to the EchoTip® Ultra Fiducial Needle (k111895). Both devices are composed of pure gold fiducials (e.g., tissue markers) preloaded within a delivery system intended to be introduced through an ultrasound endoscope. Once deployed, the radiopaque fiducials permanently mark soft tissue for therapeutic procedures.

The delivery system (i.e., needle, sheath, handle, and stylet) of the subject EchoTip® Ultra Fiducial Needle is substantially equivalent to the EchoTip® Ultra Fiducial Needle (k111895). Both are dimpled, endoscopic ultrasound needles that may be used to inject materials into tissues. No changes have been made to the implantable fiducials. Minor modifications have been made to the delivery system of the EchoTip® Ultra Fiducial Needle. Specifically, geometric, dimensional and tolerance changes have been made to the laser cut track with notch the needle sheath and the needle tip to enhance fiducial delivery. The modified ECHO Tip Ultra Fiducial needle is substantially equivalent to the referenced Wilson-Cook Fiducial needle with respect to technological characteristics and Intended Use, Indications for Use, method of operation, fundamental scientific technology and labeling.

Discussion of Tests and Test Results

Potential new risks due to the modifications to the cleared device were identified and evaluated. Cook conducted verification and validation testing specific to the risks identified to ensure that risks were mitigated and the device continued to perform as intended.

Conclusions Drawn from the Tests

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

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

June 20, 2014

Wilson-Cook Medical
% Ms. Marge Walls-Walker
Senior Regulatory Specialist – Engineering
4900 Bethania Station Road
WINSTON- SALEM NC 27105

Re: K141356
Trade/Device Name: ECHO Tip Ultra Fiducial Needle
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU, FCG
Dated: May 22, 2014
Received: May 23, 2014

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. 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.

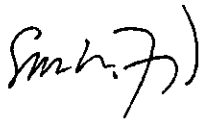
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K141356

Device Name
ECHO Tip Ultra Fiducial Needle

Indications for Use *(Describe)*
Intended to implant fiducials under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.

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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