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

Wilson-Cook Medical, Inc.
Ms. Marge Walls-Walker
Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

JUL 27 2015

Re: K033754
Trade/Device Name: TRACER METRO SMART WIRE GUIDE
Modification to Wilson-Cook Wire Guide
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated (Date on orig SE ltr): November 25, 2003
Received (Date on orig SE ltr): December 1, 2003

Dear Ms. Walls-Walker,

This letter corrects our substantially equivalent letter of December 30, 2003.

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 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. 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

510(k) Number (if known): K 033754

Device Name: Wilson-Cook Tracer Metro Smart Wire Guide

Indications for Use:

The Tracer Metro Smart Wire Guide is intended to assist in cannulation of the billary and pancreatic ducts and to aid in bridging difficult strictures during ERCP.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only ✓ OR Over-the-Counter ____
(Per 21 CFR § 801.109

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033754

DEC 3 0 2003

K033754

ATTACHMENT F: 510(k) Summary of Safety and Effectiveness

SPONSOR:	Wilson-Cook Medical 4900 Bethania Station Road Winston-Salem, NC 27105
CONTACT/SUBMITTER:	Marge Walls-Walker Regulatory Affairs Specialist [336] 744-0157 Ex.290
DATE OF SUBMISSION:	November 25, 2003
DEVICE:	Tracer Metro Smart Wire Guide
Trade Name:	Tracer Metro Smart Wire Guide
Common Name:	Wire Guide
Classification:	Endoscope and/or Accessories, Class II 21 CFR § 876.1500. 78 KOG
PREDICATE DEVICES:	Wilson-Cook Wire Guide (k9910497)
INTENDED USE:	Wilson-Cook's Tracer Metro Smart Wire Guide is intended to assist in cannulation of the biliary and pancreatic ducts and to aid in bridging difficult strictures during ERCP.
DEVICE DESCRIPTION:	The proposed Tracer Metro Smart Wire Guide is a modification to existing wire guides currently marketed by Wilson-Cook. The Tracer Metro Smart Wire Guide is .035" in diameter and is compatible with a full range of Wilson-Cook accessories.
COMPARISON OF CHARACTERISITICS:	We believe the proposed device to be substantially equivalent to currently marketed Wilson-Cook wire guides as cleared per k910497.
PERFORMANCE DATA:	We believe the proposed device to be substantially equivalent to the named predicate in terms of performance characteristics tested and biocompatibility.