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. Margaret J. Posner
Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, North Carolina 27105-4191

JUL 27 2015

Re: K030618
Trade/Device Name: Wilson-Cook Celiac Plexus Neurolysis Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia conduction needle
Regulatory Class: II
Product Code: BSP, GAA
Dated (Date on orig SE ltr): February 14, 2003
Received (Date on orig SE ltr): February 26, 2003

Dear Ms. Posner,

This letter corrects our substantially equivalent letter of May 27, 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): K030618

Device Name: Wilson-Cook Celiac Plexus Neurolysis Needle

Indications For Use:

The Wilson-Cook Celiac Plexus Neurolysis Needle is used to deliver neurolysing agents to the celiac plexus under guidance by endoscopic ultrasound. It is supplied sterile and is intended for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030618

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

RE: PREMARKET NOTIFICATION FOR THE WILSON-COOK CELIAC PLEXUS NEUROLYSIS NEEDLE

K030618

9. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 27 2003

Submitted By:
Margaret J. Posner, Regulatory Affairs Specialist
Wilson-Cook Medical Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105-4191
336.744.0157

Names of Device:

Trade Name:	Wilson-Cook Celiac Plexus Neurolysis Needle
Common/Usual Name:	Celiac Plexus Neurolysis Needle
Classification Name/Code:	Needle, Aspiration and Injection, Disposable; 21 CFR § 878.4800 (GAA); Class II

Predicate Devices:
The Wilson-Cook Celiac Plexus Neurolysis Needle is comparable to predicate devices including the Wilson-Cook Variable Length GI Injection Needle (K941305), the Wilson-Cook Endoscopic Ultrasound Needle (K934356), and the InjecTx PercuTx- Injection/Aspiration Needle Probe/Device (K994151).

Device Description:
The Wilson-Cook Celiac Plexus Neurolysis Needle is comprised of a stainless steel echogenic pencil point needle with four side openings toward the tip. The handle allows a stroke of approximately 8-cm to advance the needle into position. The outer sheath of the device is comprised of polytetrafluoroethylene.

Intended Use:
The Wilson-Cook Celiac Plexus Neurolysis Needle is used to deliver neurolysing agents to the celiac plexus under guidance by endoscopic ultrasound. It is supplied sterile and is intended for single use only.

Substantial Equivalence:
The Wilson-Cook Celiac Plexus Neurolysis Needle is comparable to predicate devices with similar technological characteristics and intended use, specifically to perform endoscopic injection procedures.

Discussion of Tests and Test Results:
The Wilson-Cook Celiac Plexus Neurolysis Needle underwent simulated use testing and clinical evaluation. Test results provide reasonable assurance the device will perform in accordance with its intended use.

Conclusion:
Being similar to predicate devices with respect to intended use and technology, and having test results that indicate the device will perform in accordance with its intended use, the Wilson-Cook Celiac Plexus Neurolysis Needle meets the requirements for 510(k) substantial equivalence.