McKinley Medical

APR 1 2 2006

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K 060119

510(k) Summary of Safety and Effectiveness – Traditional 510(k) for the McKinley Saturation Catheter™

Date Prepared:	6 January 2006
Contact for Questions:	John Chappell
Trade Name:	McKinley Saturation Catheter™
Common Name:	Infusion catheter
Classification Name:	Anesthesia conduction catheter
Classification Panel:	Anesthesiology
Device Classification Regulation Number:	Class II, 868.5120
Panel:	73
Product Code:	BSO
Predicate Devices Demonstrating Substantial Equivalence:	Micor Wundcath Conduction Catheter, K031600 & K003966 I-Flow Soaker Catheter, K994374

Statement of Substantial Equivalence:

The McKinley Saturation Catheter™ is substantially equivalent to the Micor Wundcath Conduction Catheter (K031600 & K003966) and the I-Flow Soaker Catheter (K994374).

The McKinley Saturation Catheter™ is intended for use as follows:

The McKinley Saturation Catheter™ is intended for continuous and/or intermittent infusion of pain medication to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, subcutaneous or percutaneous.

Summary Description of the McKinley Saturation Catheter™

The McKinley Saturation Catheter™ is a single patient use disposable infusion catheter, intended for connection to an infusion device, used to deliver pain medication to a patient for pain management.

The McKinley Saturation Catheter™ is a flexible, tubular infusion catheter with multiple holes located throughout the fenestrated segment along the distal end of the catheter. The catheter will be available in different sizes (varying length of fenestrated segment, number of holes, diameter of catheter body), as appropriate for use in a variety of catheter placements.

The McKinley Saturation Catheter™ connects to an infusion device via a proximal luer-lock connector.

The materials contained in the McKinley Saturation Catheter™ are substantially equivalent to those contained in the legally-marketed predicate devices.

The catheter package may include components that are legally marketed (either pre-amendment or that have been granted permission to market via the premarket notification regulation), such as an introducer needle, syringe, adhesive strips or dressing.

Conclusion:

The McKinley Saturation Catheter™ does not raise any new safety and efficacy concerns when compared to the predicate devices that are already legally marketed. The intended use, function, materials and performance of the McKinley Saturation Catheter™ are substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2006

Mr. John Chappell
Regulatory Affairs
McKinley Medical, LLC
4080 Youngfield Street
Wheat Ridge, Colorado 80033

Re: K060119
Trade/Device Name: McKinley Saturation Catheter™
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 11, 2006
Received: January 17, 2006

Dear Mr. Chappell:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060119

Device Name: McKinley Saturation Catheter™

Indications for Use:

The McKinley Saturation Catheter™ is intended for continuous and/or intermittent infusion of pain medication to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, subcutaneous or percutaneous.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible]ology, General Hospit[illegible]
[illegible] Dental Devices

[illegible] K060119