APR - 5 2004

510(k) Summary

K040029

Submitter: InjectiMed, Inc.
2737 Palma Drive
Ventura, CA 93003
Phone: 805-658-1601

Contact: George C. Brdlik
Vice President, Quality Assurance & Regulatory Affairs
Phone: 760-390-3298

Proposed Device Identification and Classification:

Proprietary Name: Frontline Medical Products SafetyNet™ Guidewire Introducer

Common Name: Guidewire Introducer

Classification Name and Reference: Catheter Introducer, § 870.1340

Classification Panel: Cardiovascular

Product Code: DYB

Regulatory Class: II

Performance Standards: No performance standards have been promulgated under Section 514

Predicate Devices

- Hart Enterprises Single Wall Introducer Needle (K843719)
- Manan Manufacturing Co. GWI Guide Wire Introducer (K851834)
- Needletech, Inc. Guidewire Introducer Needle (K031173)
- Medamicus Axia RSN™ Guidewire Introducer Safety Needle (K011085, K020563 and K022689)

Intended Use

The Frontline Medical Products SafetyNet™ Guidewire Introducer is intended for single use, for percutaneous introduction and placement of guidewires in vascular procedures, with provision of a feature enabling the user to shield the needle point after use to reduce the risk of accidental sharps injury.

Device Description

The Frontline Medical Products SafetyNet™ Guidewire Introducer is a sterile, single-use disposable device, available in gauge sizes from 18G to 21G and usable lengths up to 2.75." The 18G product is compatible with guidewires up to 0.038" diameter; the 21G is compatible with guidewires up to 0.021" diameter. The product consists of a conventional hypodermic needle-type guidewire introducer with molded plastic luer hub, modified to accept additional components to provide a needle protection feature. The additional components create a spring-loaded molded plastic safety guard assembly that is stored within a semi-rigid housing prior to deployment. After the needle is placed in the blood vessel and the guidewire is introduced, the user deploys the safety guard with a one-handed technique by squeezing two opposing tabs on the housing. This causes the safety guard to move forward to the end of the needle, when a hinged trap within the safety guard drops over the needle point, and is held in place by the spring. The safety guard is restrained from moving off the end of the needle by means of a sliding rigid bushing contained within the safety guard, that stops when reaching a small deformation (bump) that has been created on the distal end of the needle cannula during manufacturing. The used product is then disposed of in a sharps container according to routine policies and procedures. The deployed safety guard provides a reduced risk of accidental needlestick injury. The product will be packaged as single sterile units, or may be provided in bulk non-sterile form to manufacturers of procedure kits for inclusion as an accessory component.

Biocompatibility and Performance Testing

Biocompatibility testing on the Frontline Medical Products SafetyNet™ Guidewire Introducer included all tests required to satisfy ISO 10993 and FDA Memorandum G95-1 requirements. The product's fluid path components are considered to be Externally Communicating, Circulating Blood, with limited contact duration.

Performance testing has demonstrated that the Frontline Medical Products SafetyNet™ Guidewire Introducer has met the functional requirements and specifications for the device.

*** * * * * End of 510(k) Summary * * * * ***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2004

InjectiMed, Inc.
c/o Mr. George C. Brdlik
GCB Enterprises
Vice President, Quality Assurance & Regulatory Affairs
6442 Merlin Drive
Carlsbad, CA 92009

Re: K040029
Frontline Medical Products SafetyNet™ Guidewire Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 6, 2004
Received: January 8, 2004

Dear Mr. Brdlik:

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 (301) 594-4648. 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/dsma/dsmamain.html.

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K040029

Device Name: Frontline Medical Products SafetyNet Guidewire Introducer

Indications for Use:

The Frontline Medical Products SafetyNet™ Guidewire Introducer is intended for single use, for percutaneous introduction and placement of guidewires in vascular procedures, with provision of a feature enabling the user to shield the needle point after use to reduce the risk of accidental sharps injury.

Prescription Use ✓ **(Part 21 CFR 801 Subpart D)** **AND/OR** **Over-The-Counter Use** _____ **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes

Sign-Off)
of Cardiovascular Devices

510(k) Number K040029