VIII. Premarket Notification 510(k) Summary

Submitted by:	InjectiMed Inc 2737 Palma Drive Ventura, CA 93003
Contact person:	Thomas C. Kuracina President
Date prepared:	December 20, 2007
Device proprietary name:	SafetyNET Guidewire Introducer
Common name:	Percutaneous Guidewire Introducer
Classification name:	Manual surgical instrument for general use 21 CFR Sec. 878.4800
Predicate devices:	SafetyNET Guidewire Introducer (K040029) Light Saber Introducer Needle (K013040)
Description of the device:	A needle and hub device for the percutaneous introduction of a guide wire, with a hub modification to allow one-handed activation of a sheath to cover the needle and help prevent accidental needle sticks during use and disposal.
Intended use:	A percutaneous guidewire introducer for vascular and non-vascular procedures with activating safety shield to reduce needle stick injury during use and disposal.
Characteristics:	Sterile, single-use, disposable stainless steel needle with modified polycarbonate hub/spring assembly
Testing	Product and materials meet all applicable test requirement per ISO 10993-1

AUG - 8 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

InjectiMed, Inc.
% Washington Regulatory Consultants
Mr. Richard Hunter, MS, RAC
5616 Mariola Place, NE
Albuquerque, New Mexico 87111

AUG - 8 2008

Re: K073664
Trade/Device Name: SafetyNET Guidewire Introducer
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: II
Product Code: MDM
Dated: July 7, 2008
Received: July 10, 2008

Dear Mr. Hunter:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Indications for Use Statement

510(k) Number: To be assigned

Device Name: SafetyNET Guidewire Introducer

Indications for Use: A percutaneous guide wire introducer for vascular and non-vascular procedures with activating safety shield to reduce needle stick injury during use and disposal.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K073664