JUL 2 3 2003

K 031173

510 (k) SUMMARY

1. Submitter's Name / Address:

NeedleTech Products, Inc.
81 West Street
Attleboro, MA 02703

Telephone: 508-431-4000
FAX: 508-431-2156
e-Mail: rtripp@needletech.com

Contact Person: Rick Tripp
Product Assurance Manager

Submission Date: May 5, 2002

2. Device Name:

Trade Name: NeedleTech Guidewire Introducer Needle
Common Name: Percutaneous Introducer Needle

3. Predicate Devices: Terumo *Neolus* Needle
Medtronic *Disposable Hypodermic Needle Electrode*
MINIRAD *Light Saber* Introducer Needle
Manan *Blunt Needle*

4. Device Description:

The NeedleTech Guidewire Introducer Needle consists of a stainless steel cannula with an attached plastic luer lock hub on one end and a ground point or blunt tip on the other end. The device is intended to be supplied non-sterile and packaged in bulk .

5. Intended Use:

The guidewire introducer needles are intended to be single-use disposable introducers/cannula for percutaneous introduction and placement of guidewires in vascular procedures.

6. Substantial Equivalence:

The NeedleTech Guidewire Introducer Needle is substantially equivalent to a combination of its predicate devices, with the exception of minor differences in size and general indications for use, which raise no new issues regarding safety of effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2003

Mr. Rick Tripp
Product Assurance Manager
NeedleTech Products, Inc.
81 West Street
Attleboro, Massachusetts 02703

Re: K031173
Trade/Device Name: NeedleTech Guidewire Introducer Needle
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: I
Product Code: GDF
Dated: April 11, 2003
Received: May 8, 2003

Dear Mr. Tripp:

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) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510K Number (if known): K031173

Device Name: NeedleTech Guidewire Introducer Needle

Indications For Use:

The guidewire introducer needles are intended for use as introducers/cannula for percutaneous introduction and placement of guidewires in vascular procedures.

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K031173

(Optional Format 3-10-98)