K030135

JUL 15 2003

7.0 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2375

Contact: Amy K. Smith, RA Specialist

DEVICE NAME: Safety Introducer Needle

COMMON OR USUAL NAME: Guidewire introducer needle

DEVICE CLASSIFICATION: Catheter Introducer, 21 CFR 870.1340, Product Code DYB

PREDICATE DEVICE:

Medamicus, Inc.
Medamicus Guidewire Introducer Safety Needle, K011085
B. Braun Medical Inc.
Introcan® Safety™ IV Catheter, K021094

DESCRIPTION: The Safety Introducer Needle consists of a standard needle with an user-activated safety mechanism clip, clip puller and needle hub. The Safety Introducer Needle ranges in size from 18 – 21 gauges and has needle lengths between 1.5 – 2.75 inches. The needle can be made with an echogenic tip. An echogenic tip allows the tip of the needle to be located using Ultrasound techniques. The needle hubs are color coded to aid in recognition of needle gauge size. The safety clip mechanism reduces the risk of accidental needlestick injuries by shielding the needle. The safety clip mechanism will activate once the puller is pulled down the length of the needle.

INTENDED USE: The Safety Introducer Needle is an anti-needlestick device that provides access to the vascular system for the introduction of a guidewire.

SUBSTANTIAL EQUIVALENCE: The B. Braun Medical Inc. Safety Introducer Needle is similar to the Medamicus Guidewire Introducer Safety Needle (K011085) in indications for use and other

application features such as needle size and guidewire sizes accepted. The Safety Introducer Needle is substantially equivalent to the Introcan Safety IV Catheter in materials and function of the safety clip mechanism.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2003

B. Braun Medical, Inc.
c/o Ms. Amy K. Smith
901 Marcon Blvd.
Allentown, PA 18109

Re: K030135
Safety Introducer Needle
Regulation Number: 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 1, 2003
Received: May 5, 2002

Dear Ms. Smith:

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.

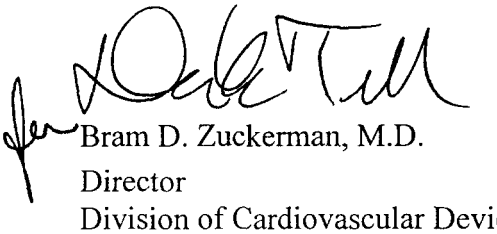
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4548. 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). 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,



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

Enclosure

Indications for Use Statement

510(k) Number (if known): K030135

Device Name: Safety Introducer Needle

Indications For Use:

The Safety Introducer Needle incorporates an active safety clip mechanism designed to minimize inadvertent needlesticks when the needle is used to introduce a guidewire.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030135