BEECH®

K972469

510(k) Summary

Date: 30 June 1997

AUG 27 1997

Submitter: Beech Medical Products, Inc.
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Contact Name: John Romano, President

Proprietary Name: SelfShield HN™ Self Sheathing Hypodermic Needle

Common Name: Shielded Hypodermic Needle

Classification Name: Hypodermic Single Lumen Needle

Predicate Device: Sherwood Monoject® Safety Syringe (1, 3, 6 and 12 cc sizes)

The SelfShield HN™ device incorporates a standard hypodermic needle which adapts to piston syringe standard luer fittings. The device embodies a spring loaded needle shield which automatically covers the needle tip prior to and after each use. It helps reduce the occurrence of accidental needlesticks to healthcare workers when the product is used as directed. The user activates the device by placing the tip of the shield against a rubber injection site, clockwise rotating the device by at least 40° and pushing the shield back until the needle tip penetrates into and beyond the injection site rubber plug. Once fluid, drug, agent or blood is drawn, the unit is removed from the injection site. The needle shield automatically advances covering and protecting the sharp tip for transport. The device is reactivated again against another injection site until disposed in an approved sharps container. The device is supplied sterile in a peelable Tyvek-nylon blister package.

Both the SelfShield HN™ device and the predicate device use the same hypodermic needle and are gamma sterilized , single patient use, and disposable devices. However, the needle shield of the Self Shield HN™ device automatically extends forward over the needle tip into a temporary locked position after each use whereas the predicate device's needle shield must be manually extended forward to the temporary locked position. The automatic return of the shield to the temporary locked position does not require a conscious effort by the user whereas the predicate device does. However, since the needle tip is not exposed so that it can be used to pierce the skin under visual control, the Self Shield HN™ indications are limited to non-skin transfers such as from a drug vial to the injection cap on an IV catheter. On the other hand, the predicate device can be used for both skin and non-skin administration of drugs or direct blood draw since the needle is initially exposed to view.

The results from comparative bench tests indicate that tensile loads needed to separate the shield from either the SelfShield HN™ unit or the predicate device are more than adequate in reducing the potential for failure by pulling since the loads are well above the force that can be reasonably applied by hand in a clinical setting. The SelfShield HN™ device's peak compressive load needed to expose the needle tip is approximately 10 times higher than the predicate device while in the temporary locked position.

Therefore, when transporting a filled syringe the SelfShield HN™ unit requires substantially more force to override the lock compared to the predicate device, which relies on a less robust detent feature to hold the shield in position during transport. The SelfShield HN™ device was tested in a simulated clinical test by experienced users of the predicate device. It performed as indicated in its labeling 548 times without any sharps injuries reported or failure of the shield activation feature and therefore meets the test requirements of the FDA guidance document on devices with sharps injury prevention features. The SelfShield HN™ needle was rated as very effective (score =10) by 50% and is generally rated as acceptable (score =8 and above) by 93% of the user-evaluators, who were positive about the safety and ease of use of the device. They indicated that it will repeatedly transfer fluids aseptically until easily disposed of in a sharps container and that users can be easily trained on the technique. Analysis of the data demonstrates that it can be used effectively by either left or right handed users. Among users who currently use the predicate device, the SelfShield HN™ device was rated as easier and requiring less time to use by the majority of user-evaluators and recommending it 98% of the time than the predicate device for fluid transfer applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1997

Mr. John Romano
President
Beech Medical Products, Incorporated
241 Lackland Drive
Middlesex, New Jersey 08846

Re: K972469
Trade Name: Selfshield HN Self Sheathing Hypodermic Needle
Regulatory Class: II
Product Code: FMI
Dated: June 30, 1997
Received: July 1, 1997

Dear Mr. Romano:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 972469

Device Name: Self Shield HN

Indications For Use:

The SELFSHIELD HN™ Self Sheathing Hypodermic Needle is indicated for non - patient contacting and non-skin penetrating applications such as fluid transfer from a drug vial or ampoule to an IV administration set injection site (Y-site) or an IV catheter intermittent injection cap (heparin lock).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Patricia Cucanti
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K978469

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

(Optional Format 1-2-96)