OHMEDA
THE BOC GROUP
Medical Devices Division

K974374

JAN - 2 1998

Ohmeda Inc
The BOC Group Technical Center
100 Mountain Avenue
Murray Hill NJ 07974 2005
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Attachment 8

510(k) Summary
Safe Needle Direct Transfer Device - TA-STV

Submitted by:

Ohmeda Inc.
Medical Devices Division
100 Mountain Ave.
Murray Hill, NJ 07974

November 19, 1997

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**
   Ms. Jing Zhang
   Phone: (908)771-6290 Fax: (908)771-1971

2. **Device Name and Classification:**
   Trade Name: Safe Needle Direct Blood Transfer Device, Model TA-STV
   Classification Name: Blood specimen collection device
   Classification Panel: Clinical Chemistry & Clinical Toxicology
   CFR Section: 21 CFR §862.1675
   Device Class: Class II
   Device Code: 75 JKA

3. **Substantial Equivalence:**
   The modified TA-STV is substantially equivalent to Ohmeda Inc.'s currently marketed TA-STV device.

4. **Device Description:**
   TA-STV is a direct blood transfer device which is cylindrical in shape and consists of an Ohmeda Safe Needle(TA-BPN) connected to a Vacutainer Luer Adapter from Becton Dickinson (BD), and a Sleeve Adapter solvent bonded to the TA-BPN.

5. **Intended Use of the Device:**
TA-STV is intended to be used with Ohmeda's disposable Safedraw® Closed Loop Blood Sampling kits. It allows direct transfer of blood samples from a Safedraw® blood sampling septum to an evacuated blood collection tube.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Device:**
The modified TA-STV has the same technological characteristics as the currently marketed TA-STV. They both provide the means of allowing blood samples to be transferred directly to a vacuum tube from Ohmeda Inc.'s Safedraw® Closed Loop Blood Sampling system.

Jing Zhang
Manager, Regulatory Affairs
Medical Devices Division
Ohmeda Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN - 2 1998

Ms. Jing Zhang
Manager, Regulatory Affairs
Ohmeda Inc.
100 Mountain Avenue
Murray Hill, New Jersey 07974

Re: K974374
Safe Needle Direct Blood Transfer Device, Model TA-STV
Regulatory Class: II
Product Code: JKA
Dated: November 19, 1997
Received: November 20, 1997

Dear Ms. Zhang:

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 requirements, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications For Use

510(k) Number (if known): K974374

Device Name: Safe Needle Direct Transfer Device - TA-STV

Indications for Use:

The TA-STV is intended to be used with Ohmeda's disposable Safedraw® Closed Loop Blood Sampling kits. It allows direct transfer of blood samples from a Safedraw® blood sampling septum to an evacuated blood collection tube. The use of TA-STV eliminates the user's direct exposure to blood, and reduces the risk of needle sticks.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974374

Concurrence of the CDRH, Office of Device Evaluation (ODE)

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