JUL 2 2 2004

510(k) SUMMARY

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

The assigned 510(k) number is K041232

1. Submitter's Identification:

   Gettig Pharmaceutical Instrument Company
   1 Streamside Place West
   P. O. Box 85
   Spring Mills, PA 16875

   Date Summary Prepared: November 18, 2003

2. Name of the Device:

   Trade Name: Gettig Universal Vial Access Pin

   Common Name: Vial Access Pin

   Classification Name: Set, I.V. Fluid Transfer

3. Predicate Device Information:

   A. Alaris Single Dose Dispensing Pin (K#013087)
   B. MPS Acacia Flow Ease Plastic Vented Needle (K#853212)

4. Device Description:

   The Gettig Universal Vial Access Pin is a plastic "needle" used to pierce the diaphragm of single and multi dose vials for the injection or withdrawal of fluids. It consists of a single molded piece containing a luer hub for attachment to a disposable piston syringe and plastic "needle" for piercing the diaphragm. There is also a polypropylene cover for the "needle" portion.

5. Intended Use:

   b. The intended use of the Gettig Universal Vial Access Pin is to pierce the diaphragm of single or multi dose vials to inject or withdraw fluids without the use of a needle.

      The Gettig Universal Vial Access Pins is indicated for use with standard medication vials.

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6. Summary of Technological Characteristics:

   The Gettig Disposable Syringe has the same intended use as the predicate devices. All are operated manually. The materials used for the Gettig Universal Vial Access Pin (polysulfone and polypropylene) are the same class of materials as the materials used in the Alaris Single Dose Dispensing Pin and the MPS Acacia Flow Ease Plastic Vented Needle predicate devices.

7. Non-Clinical Tests Performed for Determination of Substantial Equivalence:

   Testing from the following standards was conducted on the Gettig Disposable Syringe and the predicate devices:

   A. ISO 7886-1:1993 Sterile Hypodermic Syringes for Single Use

   B. ISO 594-1:1986 Conical Fittings With a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment, Part 1 General Requirements

   C. ISO 594-2:1991 Conical Fitting With a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment, Part 2 Lock Fittings

   D. ISO 8536-4:1998 Part 4 – Infusion Equipment for Medical Use – Infusion Sets for Single Use, Gravity Feed.

The testing results revealed the Gettig Universal Vial Access Pin to be substantially equivalent to the predicate devices.

8. Conclusion:

   The Gettig Universal Vial Access Pin has the same intended use and similar technological characteristics as the Alaris Single Dose Dispensing Pin and MPS Acacia Flow Ease Plastic Vented Needle. There are no new technological characteristics that raise any new questions of safety and effectiveness. Thus, the Gettig Universal Vial Access Pin is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2004

Mr. James A. Benz
Quality Assurance Manager
Gettig Pharmaceutical Instrument Company
One Streamside Place West
Spring Mills, Pennsylvania 16875-0085

Re: K041232
Trade/Device Name: Gettig Universal Vial Access PIN
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: May 7, 2004
Received: May 10, 2004

Dear Mr. Benz:

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.

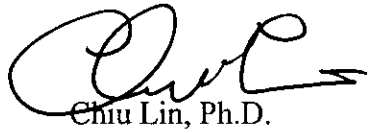
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4618. 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 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K041232

Device Name: Gettig Universal Vial Access PIN

Indications For Use:

The intended use of the Gettig Universal Vial Access Pin is to pierce the diaphragm of single or multi-dose vials to inject or withdraw fluids without the use of a needle.

The Gettig Universal Vial Access Pin is indicated for use with standard medication vials.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K041232