JAN 2 1 2004

EXHIBIT C

510(k) SUMMARY

This summary of 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 K033409.

1. **Submitter Identification:**

Gettig Pharmaceutical Instrument Company
A Division of Gettig Technologies, Inc.
One Streamside Place West
P.O. Box 85
Spring Mills, PA 16875

Date Summary Prepared:

January 12, 2004

2. **Name of the Device:**

Amersham Health Needle Guard

3. **Predicate Device Information:**

Gettig Guard, Gettig Pharmaceutical Instrument Company, Spring Mills, PA, K#000455.

4. **Device Description:**

The Amersham Health Needle Guard is a sterile, single use hypodermic needle designed to be used in conjunction with a disposable 3ml syringe. The device consists of six basic constituents, a Stainless Steel needle bonded to a Nylon hub, a Polypropylene cannula cover, a Nylon Luer attachment connected to a Polysulfone Luer hub used to connect to a syringe, and a PETG Protective sleeve. Once the Amersham Health Needle Guard is attached to a syringe, the cannula cover is removed, exposing the needle. In this condition the needle can be inserted into a vial or ampule to withdraw medication into the syringe or to administer the medication through injection. Once the needle is withdrawn from the patient, the sleeve is pushed forward to the locked safety position for disposal. The sharps safety feature is an active safety feature

5. **Intended Use:**

The intended use of the Amersham Health Needle Guard is to withdraw medications from a vial or ampule and to inject these medications subcutaneously, intramuscularlay, intravenously, or via I.V. access ports. This device may aid in the prevention of needlestick injury.

6. **Comparison to Predicate Device**:

Similarities and Differences:

The Amersham Health Needle Guard incorporates attributes from several currently marketed devices. In reference to the Gettig Guard, the action and function of the protective sleeve is similar in both use and application. Both allow for the needle to be exposed for filling the syringe with medicament, and permanent covering of the needle after injection. The difference is that the Gettig Guard allows for the protective sleeve to cover the needle prior to injection, for handling and transport, while the Amersham Health Needle Guard allows for a cannula cover to cover the needle during handling and transport.

Substantial Equivalence:

Our testing results discussed in a later section, have shown that the Amersham Health Needle Guard meets our specifications for hypodermic needles. Based on this analysis we conclude the device to be safe and effective for its intended use. The Amersham Health Needle Guard is similar in feel, function and intended use to currently marketed standard hypodermic needles. Therefore, we believe the device to be substantially equivalent to currently marketed devices.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

a) ANSI/AAMI/ISO Sterilization Standards 11137-194 Section B 3.4.1, Method 1: Dose Setting Using Bioburden Information. Bioburden and Sterilization per ISO 11737-1 and ISO 11737-2.
b) ISO 7864, "Sterile Hypodermic Needles for Single Use". Third Edition, 1993.
c) ISO 594-2, "Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings, First Edition.
d) ASTM A751 for Stainless Steel 304 Series

8. **Discussion of Clinical Tests Performed:**

Human clinical studies were not conducted on the Amersham Health Needle Guard device because the design and intended use of the devices are not significantly different to warrant these studies. However, simulated use testing was conducted on the Amersham Health Needle Guard safety feature designed to reduce the risk of needlestick accidents.

Simulated use testing was conducted to determine the effectiveness of the safety feature mechanism in preventing accidental sharp object injuries. The simulated use testing also determined the usability of the "Instructions for Use".

Attached as Exhibit #4 is the evaluation form that was utilized to record simulated use testing data, along with the results and conclusions of the study findings.

A risk analysis was assessed during the simulated testing. Based on the testing results and findings we have concluded that there were no unexpected risks in use of this device.

9. **Conclusions:**

The Amersham Health Needle Guard has the same intended use and similar technological characteristics as the predicate device. Moreover, the bench testing and simulated use testing demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Amersham Health Needle Guard is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2004

Mr. James A. Benz
Gettig Pharmaceutical Instrument Company
1 Stream Side Place West
P.O. Box 85
Spring Mills, Pennsylvania 16875-0085

Re: K033409
Trade/Device Name: Amersham Health Needle Guard
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: October 20, 2003
Received: October 27, 2003

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

K033409

Exhibit B

510(k) Number (if known): K033409

Device Name Amersham Health Needle Guard

Indications For Use:

The intended use of the Amersham Health Needle Guard is to withdraw medications from a vial or ampule and to inject these medications subcutaneously, intramuscularly, intravenously, or via I.V. access ports. This device may aid in the prevention of needlestick injury.

Prescription Use √ **AND/OR** **Over-The-Counter Use** ____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vicki Hubbard, Interim Branch Chief
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033409