OCT 0 8 2002

Exhibit C

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 K022495.

1. Submitter's Identification:

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

   Date Summary Prepared:

   July 25, 2002

2. Name of the Device:

   Trade Name: Gettig Disposable Syringe

   Common Name: Piston Syringe

   Classification Name: Piston Syringe

3. Predicate Device Information:

   A. Becton Dickinson Syringe (K#941562)
   B. Terumo Disposable Syringe (K#980181)

4. Device Description:

   The Gettig Disposable Syringe is a standard piston syringe. It consists of a calibrated hollow barrel and a moveable plunger. At one end of the barrel there is a male connector (nozzle) for the female connector (hub) of a hypodermic single lumen needle.

5. Intended Use:

   The intended use of the Gettig Disposable Syringe is to inject fluids into, or withdraw fluids from, the body.

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 Disposable Syringe (polycarbonate

and Santoprene) are the same as the Polycarbonate used in the Becton Dickinson Syringe and the Santoprene used in both mentioned predicate devices.

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

   The following standards testing were 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

The testing results revealed the Gettig Disposable syringe to be substantially equivalent to the predicate devices.

8. Conclusion:

   The Gettig Disposable Syringe has the same intended use and similar technological characteristics as the Terumo Disposable Syringe and Becton Dickinson Syringe. There are no new technological characteristics that raise any new questions of safety and effectiveness. Thus, the Gettig Disposable Syringe 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

OCT 0 8 2002

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

Re: K022495
Trade/Device Name: Gettig Disposable Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 25, 2002
Received: July 29, 2002

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 and additionally 21 CFR Part 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" (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,

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

Enclosure

510(k) Number (if known): K022495

Device Name Gettig Disposable Syringe

Indications For Use:

The Gettig Disposable Syringe, with or without a hypodermic single lumen needle, is used for injecting fluids into or withdrawing fluids from the body. The syringe is designed for manual use.

(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: K022495

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)