SEP 11 1997 K972285

Section A

510 (k) Summary

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

Establishment Registration Number - #2511670

Telephone Number - 814-422-8892
Fax Number - 814-422-8011
email - kfee@gettig.com

Contact Person: Kevin Fee

Date of Application - June 17, 1997

Device Name:

• Proprietary Name --	Gettig Styrl-Ject® Delivery System
• Common Name --	Hypodermic Syringe Cartridge
• Proposed Classification Name--	Syringe, Cartridge 21 CFR Sec. 872.6770
• Class II	
• Product Code --	76 E J I

Predicate Device - Substantial Equivalence
The Gettig Styrl-Ject® Delivery System is similar to various predicate and pre-amendment devices currently and previously marketed having the same intended use for medicament administration. The device has attributes similar to the Astra Aspirating Syringe (K851903), the Terumo Hypodermic Syringe (K771205), the Wyeth Tubex® (Pre-amendment), and the Monoject® Prefilled Syringe (K812934).

Device Description
The Gettig Styrl-Ject® Delivery System is a sterile, single use hypodermic syringe cartridge device designed to be similar to current single use products. The device consists of two basic constituents - a previously filled glass carpule, and plastic syringe. The carpule features a plastic retainer with a frangible button. When ready to use, the carpule retainer button is snapped off, exposing the rubber diaphragm insert. Until, the button is snapped the carpule needle path remains sterile, thus eliminating the need for an alcohol swab. The plastic syringe is also sterile until ready for use via the plunger rod encapsulating the needle rear extension. After removal of the threaded plunger rod, the carpule is then inserted into the clear plastic syringe allowing the syringe needle rear extension to puncture the rubber diaphragm creating a path for medicament administration. Then the syringe plunger rod is engaged with the plunger and the cover (needle or luer) is removed, to allow aspiration and injection. The syringe can be configured for a variety of needle sizes for subcutaneous injection as well as for I.V. applications via butyl and needleless access ports.

Biocompatibility
Reasonable assurance of biocompatibility of the materials comprising the device is provided by their established history in medical product manufacturing, USP class VI designations, and DMF file information for the materials (see Section H - Appendix).

Materials
See Section F for materials description and Section H Appendix for material specifications.

Physical Properties
See Section H Appendix for physical properties

Statement of Intended Use
The intended use of the device is to inject medicaments subcutaneously, intramuscularly, or via I.V. access ports. This device is intended for all adult patient populations based upon the appropriate needle size selection by the physician or clinician, and is governed by the specific drug being administered. Any pediatric applications is at the discretion of the physician and governed by the specific drug being administered.

Indication Statement Differences
There are no differences for indications with the predicate device(s).

Comparison of Technologies, Materials, and Design with Predicate Device(s).
See Section E, Tables 11 & 12 for comparison data.

Performance Bench Tests and Data to Show Safety and Effectiveness
The non-clinical bench tests performed on the Gettig Styrl-Ject® Delivery System are the same protocols and standards used for the evaluation of our standard syringe products. See Section C for performance data and Section H Appendix for performance test summary.

Listing of Performance Bench Tests

Carpule Leak Test
- Vacuum Dye
- Air Gauge - Federal DimensionAire

Button Snap Tests
- Before Sterilization
- After Sterilization

Glass Neck Snap-Off
- Schott revision 1 & 2

Plunger Extrusion Force
- Using O-Ring Universal Plunger
- Chattilon Gauge

Needle Sharpness - 22 ga & 25 ga
- Penetration
- Drag

Needle Rear Extension
- Penetration

Needle Retention - Instron Pull
- 22 ga & 25 ga

Cover Pull-off Force - Instron Pull
- 22 ga & 25 ga

Needle Rear Extension Coring
- 22 ga & 25 ga Rear Beveled
- 22 ga Blunt w/Rear Blunt

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1997

Mr. Kevin Fee
Gettig Pharmaceutical Instrument Company
1 Stream Side Place West
Spring Mills, Pennsylvania 16875-0085

Re: K972285
Trade Name: Gettig Styrl-Ject Delivery System
Regulatory Class: II
Product Code: EJI
Dated: June 17, 1997
Received: June 19, 1997

Dear Mr. Fee:

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):_____

Device Name: Gettig Styrl-Ject® Delivery System

Indications For Use:

The indications for use of the device is to inject medicaments subcutaneously, intramuscularly, or via I.V. access ports. This device is intended for all adult patient populations based upon the appropriate needle size selection by the physician or clinician, and is governed by the specific drug being administered. Any pediatric applications is at the discretion of the physician and governed by the specific drug being administered.

There are no differences for indications with the predicate device(s).

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number _____

Prescription Use_____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)