MAR 17 2000

K993609

510(k) Summary of Safety and Effectiveness For SOLOGARD® LOCKING PLUS Syringe

October 20, 1999

CONTACT PERSON:

Patrick Grant, Jr.
SafeGard Medical Products, Inc.
52 Dragon Court
Woburn, MA 01801
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DEVICE NAME:

Trade name: SOLOGARD® LOCKING PLUS Syringe
Common & Classification name: Piston Syringe

PREDICATE DEVICE:

Becton Dickinson Single Use Hypodermic Syringes

PRODUCT DESCRIPTION:

The SOLOGARD® LOCKING PLUS Syringe is a sterile, single-use, disposable hypodermic syringe with a plunger locking feature to prevent the accidental reuse of the syringe. It is manufactured in sizes of 1, 2.5, 3, 5, & 10 ml with a LuerLock connector and is supplied without needle.

INTENDED USE:

The syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.

COMPARISON TO PREDICATE DEVICE:

The SOLOGARD® LOCKING PLUS Syringe is designed with a locking feature which detains the plunger after it is depressed and prevents the plunger withdrawal for a subsequent accidental reuse. All other aspects of the design do not vary significantly from the predicate device.

EQUIVALENCE:

In order to demonstrate that the locking feature did not effect the safety and efficacy of the device design, engineering analyses of the fluid flow and dynamometer and simulated use testing of the locking feature were conducted. Results indicated that the device performance was equivalent to that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

Patrick Grant, Jr.
Chief Financial Officer
SafeGuard Products, Incorporated
52 Dragon Court
Woburn, Massachusetts 01801

Re: K993609
Trade Name: SOLOGARD® LOCKING PLUS Syringe
Regulatory Class: II
Product Code: MEG
Dated: February 15, 2000
Received: February 17, 2000

Dear Mr. Grant, Jr.:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

Indications for Use Statement

510(k) Number (if known): K993609

Device Name: SOLOGARD® Locking Plus Syringe

Indications For Use:

These syringes are intended for use by health care professionals for general purpose fluid aspiration/injection. The devices contain a piston locking mechanism which aids in the prevention of the accidental reuse of the syringe.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Rebecca Cucente
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993609

(Optional Format 1-2-96)