

K 971077

MAY 15 1998

510(k) SUMMARY
CoverTip Safety Syringe™
March 21, 1996

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87 and the SMDA.

1.0 Submitter of 510(k) and Manufacturer

Name: Medisys Technologies, Incorporated
9624 Brookline Avenue
Baton Rouge, LA 70809

Attention: Mr. Kerry Frey
Telephone: (504) 926-0422
Facsimile: (504) 926-1586

Consultant:

Joel S. Faden, Ph.D.
Joel S. Faden, Ph.D., Inc.
Telephone: 301-881-9139
Facsimile: 301-881-9249

Dr. Faden is an independent consultant to Medisys Technologies, Incorporated.

2.0 Name of Device

2.1 Trade/Proprietary Name

CoverTip Safety Syringe

2.2 Common/Usual Name

Piston Syringe

2.3 Classification Name

Piston Syringe (21 C.F.R. 880.5860, class II)

3.0 Reason for Submitting the 510(k)

We are submitting this 510(k) to notify you of our desire to commercially distribute for the first time the CoverTip Safety Syringe.

4.0 Device Description

The CoverTip Safety Syringe is a standard piston syringe which incorporates a passive sharp safety needle covering feature. The syringe automatically deploys a plastic cover (sheath) over the needle as the injection is completed and prior to the needle's removal from the tissue. The sheath protrudes beyond the end of the needle, shielding the user and patient from the sharp after removal. The sheath effectively blunts the end of the needle.

5.0 Indications for Use & Intended Use

5.1 Indications For Use

The CoverTip Safety Syringe™ is indicated for use in the administration of an intramuscular (IM) injection.

5.2 Intended Use

The CoverTip Safety Syringe™ is a piston syringe intended for use in the administration of an intramuscular (IM) injection.

6. Substantial Equivalence

The CoverTip Safety Syringe is substantially equivalent, as defined in 21 U.S.C. Section 360c(i), to legally marketed predicate devices.

The CoverTip Safety Syringe has technological characteristics substantially equivalent to those of legally marketed predicate devices. Provides in Table 1 is a tabulated comparison of the essential technological characteristics of the CoverTip Safety Syringe and several legally marketed predicate devices.

Table 1
Technological Characteristics
CoverTip Safety Syringe vs. Predicate Devices

Device Name	CoverTip Safety Syringe	Standard Syringe	Safety-Lok Syringe	Punctur-Guard
Manufacturer	Medisys Tech.	Becton Dickinson	Becton Dickinson	Bioplexus
510(k) #	current document	pre-enactment	K920321	K895024
Indicated for IM injection	yes	yes	yes	no
Standard piston syringe	yes	yes	yes	no - blood collection needle
Safety feature	sheath over needle extended beyond tip	none	barrel size tube extended over needle	tube inside needle extended beyond tip
Aim of safety feature	blunt the needle	not applicable	blunt the needle	blunt the needle

The CoverTip Safety Syringe was shown to have the same Indication for Use and Intended Use as predicate devices. Further, as indicated in the table the technological characteristics of the CoverTip Safety Syringe and predicate devices are substantially equivalent. Performance data presented demonstrated that the CoverTip Safety Syringe is substantially equivalent to legally marketed predicate devices. Performance testing conducted demonstrated that the design and manufacture of the CoverTip Safety Syringe meets or exceeds the requirements of relevant international standards. Next, the performance testing demonstrated that the deployed needle sheath of the CoverTip Safety Syringe is substantially equivalent in its needle blunting capability to that found in legally marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 1998

Medisys Technologies, Incorporated
C/O Joel S. Faden, Ph.D.
Consultant
Joel S. Faden, Ph.D., Incorporated
11605 Hitching Post Lane
Rockville, Maryland 20852

Re: K971077
Trade Name: Covertip Safety Syringe
Regulatory Class: II
Product Code: MEG
Dated: March 20, 1998
Received: March 23, 1998

Dear Dr. Faden:

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 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). 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.

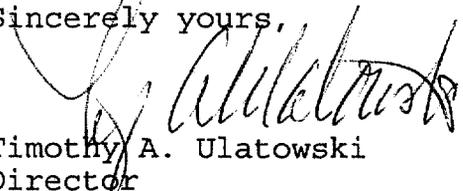
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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) 594-4692. 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" (21CFR 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/dsma/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

Device Name: CoverTip™ Safety Syringe

Indications For Use:

The CoverTip™ Safety Syringe is indicated for use in the administration of an intramuscular (IM) injection. The CoverTip™ Safety Syringe aids in the prevention of accidental needle sticks by passively and automatically deploying a sheath that covers the sharp needle upon completion of the injection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

OR Over-The-Counter:

Patricia Accardi
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971077