

K970547

The Isolyser Co., Inc.

JUL 18 1997

510(k) SUMMARY

As required by 21 C.F.R. § 807.92 the following is a 510(k) Summary for the Isolyser SDS container:

(1) Submitter's Name/Contact Person:

Tom Bonner
Vice President, Regulatory Affairs and Quality Assurance
The Isolyser Company, Inc.
650 Engineering Drive
Technology Park
Norcross, GA 30092
(800) 777-7977
Date Prepared: February 11, 1997

(2) Device Name and Classification:

Isolyser Syringe Disposal System
Sharps Container without Secondary Container
Accessory to hypodermic needle

(3) Legally Marketed Device to Which Claim Equivalence:

Isolyser Sharps Management System ("SMS") 1000
(K943626) cleared March 14, 1995 by FDA.

(4) Device Description:

The Isolyser Syringe Disposal System (SDS) has the same uses as other sharps containers in commercial distribution: to provide safe and effective disposal of medical sharps. The major difference between the Isolyser SMS 1000 and the SDS relate to the setting in which the device will be used. The SDS is intended for use in non-clinical settings while the Isolyser SMS 1000 is used in clinical settings.

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As is true for the Isolyser SMS 1000, the SDS is closable, puncture resistant and leakproof on the sides and the bottom. The fluorescent orange BIOHAZARD warning labels are clearly visible with lettering in contrasting color and are affixed by adhesive to the SDS containers. Like the SMS 1000, the SDS container maintains a stable and upright position. There is no feature to bend, break, or shear the needle off the hub of the syringe.

When the SDS is full, the user adds water to the SDS to activate the "Gel-loc" system. After replacing the cap on the SDS, the user shakes the container well. The user then places the SDS into the carton provided and seals it with tape. The user then disposes of the sealed carton according to local, state and federal laws.

The disposal methods for the SMS 1000 and the SDS are quite similar. As is true for SMS 1000, the SDS containers are designed so that no user is required to reach by hand into the container to retrieve the contaminated reusable sharps. As indicated on all labels for SDS containers, safe and effective disposal of the waste is easily accomplished.

(5) Intended Use for Isolyser SDS

The Isolyser SDS is intended for use in non-clinical settings for the disposal of contaminated sharps.

(6) Technical Characteristics for Isolyser SDS

The SDS container has essentially the same technical characteristics as the Isolyser SMS 1000. The materials and method of manufacturing the SDS container itself is nearly identical to the methods used to manufacture the SMS 1000. The only technical difference for the SDS product relates to the method of disposal. To dispose of the SDS, the user applies the Isolyser disposal Gel-Loc System for disposal. To dispose of the Isolyser SMS 1000, the user adds a catalyst to the contents before disposal. This change does not materially affect the safety or effectiveness of the device.

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(7) Conclusions Drawn from Studies

The data demonstrate that the performance of the Isolyser SDS is substantially equivalent to other legally marketed sharps containers.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tom Bonner
Vice President
The Isolyser Company, Incorporated
4320 International Boulevard, NW
Norcross, Georgia 30093

JUL 18 1997

Re: K970547
Trade Name: Isolyser SDS Sharps Container
Regulatory Class: II
Product Code: FMI
Dated: May 19, 1997
Received: May 20, 1997

Dear Mr. Bonner:

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.

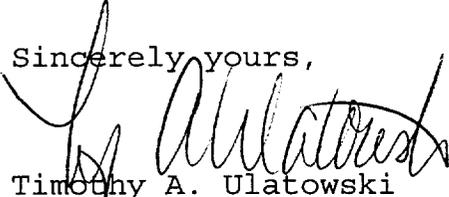
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

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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: Isolyser Syringe Disposal System (SDS)

Indications for Use:

The Isolyser SDS is a sharps container intended for use in non-clinical settings for the disposal of contaminated sharps.

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

Chun S. Lin _____

(Division Sign-Off) Concurrency of CDRH, Office of Device Evaluation (ODE)
Division of **Dental, Infection Control,**
and **General Hospital Devices**
510(k) Number K970547

Prescription Use _____

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)