

NOV 30 1998

DeRoyal Industries, Inc.
TRACECART SHARPS COLLECTION CONTAINER

Revised 510(k) Summary

K983750

**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
UPON WHICH
AN EQUIVALENCE DETERMINATION COULD BE BASED**

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc.
ADDRESS: 200 DeBusk Lane
Powell, TN 37849

TELEPHONE: (423) 938-7828
CONTACT: Camille Matlock
DATE OF PREPARATION: November 16, 1998

DEVICE NAMES

NAME: DeRoyal Industries, Inc. TraceCart Sharps Collection Container
COMMON/USUAL NAME: Sharps Collection and Disposal Systems
CLASSIFICATION NAME (if known): Accessory: Hypodermic Single Lumen Needle

PREDICATE OR LEGALLY MARKETED DEVICES

Baxter
Sage Products
Devon Industries

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. TraceCart Sharps Collection Container is an accessory to a single lumen hypodermic needle. The proposed device functions in the same manner as predicate devices to provide the safe collection and containment of various types of contaminated waste and sharps such as syringes, needles, blades, and laparoscopic devices.

Device Design/Materials Used/Physical Properties: The proposed device is comprised of high-density polyethylene (HDPE). The lid is comprised of opaque polypropylene. The DeRoyal TraceCart Sharps Collection Container passed the following test methods: impact resistance, puncture resistance, overfill detection, leak resistance, stack test, stability, volume capacity, and wall material thickness.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. TraceCart Sharps Collection Container is intended for use during the generation of medical waste by providing a means of containment prior to disposal of contaminated medical waste and sharps used in various types of medical settings.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Material Description	Container: High-density polyethylene (HDPE) Lid: Opaque polypropylene lid	Similar
Sizes	15 gallon, 30 gallon, and 40 gallon	Yes
Puncture Resistant	Yes	Yes
Leak Resistant	Yes	Yes
Sterility	Non-sterile	Non-sterile



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Camille Matlock
Regulatory Affairs
DeRoy Industries, Incorporated
200 DeBusk Lane
Powell, Tennessee 37849

Re: K983750
Trade Name: DeRoyal Industries, Incorporated TraceCart
Sharps Collection Container
Regulatory Class: II
Product Code: FMI
Dated: October 22, 1998
Received: October 23, 1998

Dear Ms. Matlock:

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.

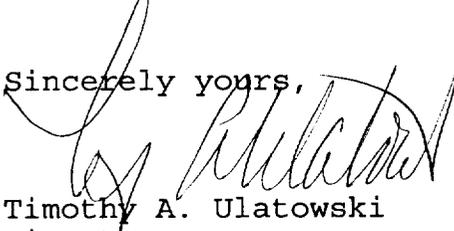
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

510(k) Number (if known): K983750

Device Name: DeRoyal Industries Inc. TraceCart Sharps Collection Container

Indications for Use:

The DeRoyal Industries Inc. TraceCart Sharps Collection Container is to be used by generators of medical waste in any health care setting where the safe collection and disposal of contaminated waste and medical sharps is required, such as in hospitals, doctors' offices, and other health care settings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin
(Division Sign-Off)
Division of ~~State~~ Infection Control,
and General Hospital Devices
510(k) Number K983750

Prescription Use _____
(Per 21 CFR § 801.109)

OR

Over-The-Counter Use X