K993089

OCT 14 1999

DeRoyal Industries, Inc.

DeRoyal Disposable Rigid Light Handle and Adapter

510(k) Summary

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) 362-6217
CONTACT: Lois Marsh
DATE OF PREPARATION: September 15, 1999

DEVICE NAMES

NAME: DeRoyal Disposable Rigid Light Handle and Adapter
COMMON/USUAL NAME: Surgical Light Handle and Adapter
CLASSIFICATION NAME (if known): Light, Surgical, Accessories (79FTA)

PREDICATE OR LEGALLY MARKETED DEVICES

Charles Polo & Co. and Devon Industries

DEVICE DESRIPTION

The DeRoyal Disposable Rigid Light Handle and Adapter function in the same manner as predicate devices in that they are intended to be used as accessories to a surgical lamp which are used to position the light for illumination in various areas of the surgical field.

Device Design/ Materials Used/Physical Properties: The DeRoyal Disposable Rigid Light Handle and Adapter are made of materials commonly used for their purposes. The light handle contains a protective shield at the base which is used to prevent the gloved hand from contacting contaminated surfaces. The protective shield may be folded and attached to the light handle to reduce space needed for packaging and storage.

DEVICE INTENDED USE

The DeRoyal Rigid Light Handle and Adapter are intended to be used as accessories to a surgical lamp. The universal adapter is used to attach the light handle to the surgical lamp when necessary while the light handle is used to position the lamp to the desired area without contaminating the gloved hand.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLYMARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Material (Light Handle)	**Plastic Polymers**	**Plastic Polymers**
Protective Shield	**Yes**	**Yes**
Rigid	**Yes**	**Yes**
Universally Adaptable	**Yes**	**Yes**
Sterility	**Sterile**	**Sterile**
Disposable	**Yes**	**Yes**
Packaged	**1 or 2 per Pack**	**1 or 2 per Pack**
Material (Adapter)	**Aluminum**	**Similar**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

Ms. Lois Marsh
Regulatory Affairs
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, Tennessee 37849

Re: K993089
Trade Name: DeRoyal Disposable Rigid Light Handle and Adapter
Regulatory Class: II
Product Code: FTA
Dated: September 15, 1999
Received: September 16, 1999

Dear Ms. Marsh:

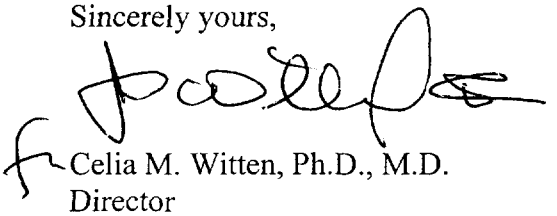
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993089

Device Name: DeRoyal Disposable Rigid Light Handle and Adapter

Indications for Use:

The DeRoyal Disposable Rigid Light Handle and Adapter are indicated for use as accessories to a surgical lamp. The adapter is to be used, when necessary, to attach the light handle to the surgical lamp. The light handle is to be used to position the light without contaminating the gloved hand.

(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 General Restorative Devices
510(k) Number K993089

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