K991525

JUL 20 1999

DeRoyal Industries, Inc.

STERILE NEONATAL BLOOD PRESSURE CUFF

510(k) Summary

Summary of the Safety and Effectiveness Information Upon Which An Equivalence Determination Could Be Based

SUBMITTER INFORMATION

NAME:	DeRoyal Industries, Inc.	TELEPHONE:	(423) 362-6217
ADDRESS:	200 DeBusk Lane	CONTACT:	Lois Marsh
	Powell, TN 37849	DATE OF PREPARATION:	April 29, 1999

DEVICE NAMES

NAME:	DeRoyal Sterile Neonatal Blood Pressure Cuff
COMMON/USUAL NAME:	Blood Pressure Cuff
CLASSIFICATION NAME (if known):	Cuff, Blood Pressure (74DXQ)

PREDICATE OR LEGALLY MARKETED DEVICES

Critikon, Ethox, and Lorin Medical

DEVICE DESRIPTION

The DeRoyal Sterile Neonatal Blood Pressure Cuff functions in the same manner as predicate devices in that it is intended to be used in conjunction with another device to determine a subject's blood pressure.

Device Design/ Materials Used/Physical Properties: The DeRoyal Sterile Neonatal Blood Pressure Cuff is made of materials commonly used for their purpose. The concept of use is that the device has an inflatable bladder in an elastic cuff (sleeve) with a mechanism for inflating and deflating the bladder. Both components, together, are used to determine a patient's blood pressure.

DEVICE INTENDED USE

The DeRoyal Sterile Neonatal Blood Pressure Cuff is indicated for use whenever non-invasive physiologic blood pressure needs to be obtained from the limbs (extremities) using the appropriate blood pressure monitor designed to operate together with the cuff.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLYMARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Main Cuff Material	**PVC Film**	**PVC Film**
Sizes	**Neonate**	**Neonate**
Disposable	**Yes**	**Yes**
Sterility	**Sterile**	**Sterile and Non-Sterile**
Number of Tubings	**1 and 2**	**1 and 2**
Pressure Range	**0-300 mmHg**	**0-300 mmHg**
Bulb Material	**PVC**	**PVC**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1999

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

Re: K991525
DeRoyal Sterile Neonatal Blood Pressure Cuff
Regulatory Class: II (Two)
Product Code: DXQ
Dated: April 29, 1999
Received: May 3, 1999

Dear Ms. Marsh:

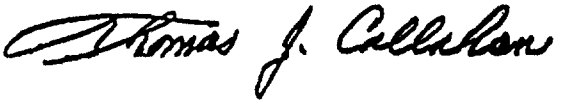
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991525

Device Name: DeRoyal Sterile Neonatal Blood Pressure Cuff

Indications for Use:

The DeRoyal Sterile Neonatal Blood Pressure Cuff is indicated for use whenever non-invasive physiologic blood pressure need be obtained from the limbs (extremities) using the appropriate blood pressure monitor designed to operate together with the cuff.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991525

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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