DeRoyal Industries, Inc.
Surgical Eye Spear

K 972693

510(k) Summary

SEP 30 1997

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

SUBMITTER INFORMATION

NAME:	DeRoyal Industries, Inc.	TELEPHONE:	(423) 938-7828
ADDRESS:	200 DeBusk Lane	CONTACT:	Camille Matlock
	Powell, TN 37849	DATE OF PREPARATION:	September 19, 1997

DEVICE NAMES

NAME:	DeRoyal Industries, Inc., Surgical Eye Spear
COMMON/USUAL NAME:	Eye Spear
CLASSIFICATION NAME (if known):	Sponge, Ophthalmic (86HOZ)

PREDICATE OR LEGALLY MARKETED DEVICE
Ultracell Medical Technologies (K923922)

DEVICE DESCRIPTION
The DeRoyal Industries, Inc., Surgical Eye Spear functions in the same manner as predicate devices in that it is comprised of an absorbent spear attached to a plastic handle.

Device Design/Materials Used/Physical Properties: The DeRoyal Industries, Inc., Surgical Eye Spear is made of materials commonly used in predicate devices. The spear is comprised of cellulose and the handle is made of a high density plastic.

Clinical Data was not required for this submission.

DEVICE INTENDED USE
The DeRoyal Industries, Inc., Surgical Eye Spear is indicated for use in ophthalmic or microscopic surgical procedures to absorb fluids from the operative field.

Characteristics & Materials	**DeRoyal Surgical Eye Spear**	Predicate Device
Sponge Material	**Cellulose**	Same
Handle Material	**High Density Polyethylene**	Same
Shape	**Triangular Sponge Head**	Same
Sponge Tip Measurements	**11/16 inch (length)** **9/32 inch (width)**	~Same
Plastic Handle Measurements	**2-3/16 inch (length)** **.092 inch - .125 inch (diameter)**	~Same
Sizes	**One Size**	Same
Sterility	**Sterile**	Same

K972693

STERILITY INFORMATION

The device shall be offered sterile. The method of sterilization is Ethylene Oxide with a Sterility Assurance Level of 10^{-6}. The maximum levels of residues of ethylene oxide, ethylene chlorohydrin, and ethylene glycol allowed to remain on the device will meet the proposed maximum residual limits stated in the Federal Register, June 23, 1978.

BIOCOMPATIBILITY TESTING

The following Biocompatibility tests were performed. All test results were deemed acceptable.

TEST	REFERENCE
Cytotoxicity	ISO 10993-1
Sensitization	ISO 10993-1
Intraocular Irritation	ISO 10993-1
Systemic Injection	ISO 10993-1 & USP Class VI
Hemolysis	ISO 10993-1
Intracutaneous Toxicity	USP Class VI
Intracutaneous Implantation	USP Class VI

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1997

Ms. Camille Matlock
Regulatory Affairs
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849

Re: K972693
Trade Name: DeRoyal Industries, Inc. Surgical Eye Spear
Regulatory Class: II
Product Code: 86 HOZ
Dated: July 17, 1997
Received: July 18, 1997

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 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) 594-4613. 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K912693

Device Name: DeRoyal Industries Inc., Surgical Eye Spear

Indications for Use:

The DeRoyal Industries Inc., Surgical Eye Spear is to be used to absorb fluids from the operative field during ophthalmic and microscopic surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David W. C. Brown

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K912693

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