DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

JUN 15 1992

Mr. Jack W. Howard
Official Correspondent
O. R. Specialties, Inc.
4749 Appletree
Tuscaloosa, Alabama 35405

Re: K921064
Trade Name: Disposable Infusion Cannulae
Regulatory Product Class: I
Product Codes: 86 HMX
Generic Name: Ophthalmic Cannulae
Dated: February 18, 1992
Received: March 5, 1992

Dear Mr. Howard:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this product.

The final classification regulation for your device was published in the Federal Register on September 14, 1988, Vol. 53, No. 178, pp. 35602-35607. A copy of this regulation is enclosed for your information. Beginning with the effective date of this regulation, manufacturers of Manual Surgical Ophthalmic Devices are exempt from the premarket notification requirements of the Act. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device's product code, generic name and regulatory class are shown above. If you are required to list your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent Manual Surgical Ophthalmic Devices may be marketed without sending a premarket notification submission to the Food and Drug Administration.

If you have any questions regarding this letter, please contact Ms. Ming-chuen Shih at (301) 427-1209 or the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Nancy C. Brogdon for

Richard E. Lippman, O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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JUL 2 1992

Mr. Jack W. Howard
Official Correspondent
O.R. Specialties, Inc.
4749 Appletree
Tuscaloosa, Alabama 35405

Re: K922180
Trade Name: Lewicky-O.R.S. Tubing
Regulatory Product Class: I
Dated: May 5, 1992
Received: May 8, 1992

Dear Mr. Howard:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1165. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Richard E. Lippman, O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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1390 Piccard Drive
Rockville MD 20850

DEC -9 1991

Mr. Jack W. Howard
Official Correspondent
O.R. Specialties, Inc.
4749 Appletree
Tuscaloosa, AL 35405

Re: K914038
Polly's Cutter J-225
Regulatory Product Class: II
Dated: September 4, 1991
Received: September 10, 1991

Dear Mr. Howard:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Richard E. Lippman, O.D., F.A.A.O.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

AUGUST 12, 1991

O.R. SPECIALTIES, INC.
ATTN: JACK W. HOWARD
4749 APPLETREE
TUSCALOOSA, AL 35405

510(k) Number: K911932
Received: 08-09-91
Product: J105 JAMES SURGICAL SYSTEM I/A PACK

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health