

K962151



SEP 18 1996

11. SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: May 31, 1996

Device Name: Ryder Lacrimal Intubation Set

Common Name: Lacrimal Intubation Set

Classification Name: Lacrimal Probe / Manual Ophthalmic Surgical Instrument per 21 CFR 886.4350

Manufacturer: Ryder International Corporation, 1426 Curt Francis Road, Arab, AL 35016

Contact: Mr. Dan Clark
Ryder International Corporation, 1426 Curt Francis Road
Arab, AL 35016
Telephone: (250) 586-1580
Fax: (205) 586-5553

Predicate: Concept 9035 Guibor Canaliculus Intubation Set

Device Description: The Lacrimal Intubation Set consists of two malleable stainless steel probes (to facilitate insertion) securely attached to a flexible silicone tube of varying thickness. The intubation set is a single-use product, sterilized by gamma radiation.

Intended Use: The Ryder Lacrimal Intubation set is valuable in the reconstruction of the lacrimal outflow system and also useful in canaliculus repair, lacrimal obstruction and complicated and uncomplicated dacryocystorhinostomy procedures.

Technological Characteristics: The design of the predicate device is such that the outside diameter of the silicone tubing is fixed while the Ryder device has variations in the outside diameter of the silicone tubing.

Summary of Safety Testing: Based on the 510(k) "Substantial Equivalence" decision-making process and the information provided herein, we conclude that the new device is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.



DEC 11 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ryder International Corp.
c/o Mr. Dan Clark
Vice President Regulatory and Quality
1426 Curt Francis Road
Arab, AL 35016

Re: K962151
Trade/Device Name: Ryder Lacrimal Intubation Set
Regulatory Class: Unclassified
Product Code: OKS
Dated: May 31, 1996
Received: June 4, 1996

Dear Mr. Clark:

This letter corrects our substantially equivalent letter of September 18, 1996.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure