

K971832

### SUMMARY STATEMENT

Barry Hale  
M-PACT Corporation  
1040 OCL Parkway  
Eudora, KS 66025  
913-542-2135  
Contact Barry Hale  
May 14, 1997

Name of Product: Sponge, Ophthalmic

M-PACT Corporation, registration number 1928508, wishes to file an intent to market sterile, single-use Eye Drain 80cc, Eye Drain 400cc, Eye Wick 8-inch, and Surgical Spears manufactured from formalized PVA sponge material. M-PACT will market the products under the trade name of IVALON®. The classification name for the devices is Sponge, Ophthalmic (per 21 CFR 886.4790).

The Eye Drain 80cc, Eye Drain 400cc, Eye Wick 8-inch, and Surgical Spears are packaged individually as a sterile, dried and compressed sponge. They are used to absorb fluids from the operative field in ophthalmic surgery.

M-PACT Eye Drain 80cc, Eye Drain 400cc, Eye Wick 8-inch, and Surgical Spears are made from formalized PVA sponge, which is a condensation product of polyvinyl alcohol and formaldehyde. Once the chemical reaction has taken place and the foam sponge has cured, the material is washed clean of any residual chemicals.

M-PACT Corporation is the manufacturer of the formalized PVA sponge. M-PACT has contracted with IPAX Corporation (Denver, Colorado) to complete the packaging processes. M-PACT contracts with Titan for sterilization services.

Although this is a new product for M-PACT, it is a product which is substantially equivalent to Eye Drain 80cc, Eye Drain 400cc, Eye Wick 8-inch, and Surgical Spears that are currently marketed in interstate commerce and which were on the market prior to the date of the enactment of the Medical Device Amendment of 1976 (May 28, 1976). The M-PACT Eye Drain 80cc, Eye Drain 400cc, Eye Wick 8-inch, and Surgical Spears are identical in size, shape, material composition and intended use as the Merocel Eye Drain 80cc, Eye Drain 400cc, Eye Wick 8-inch, and Surgical Spears currently marketed by Merocel Corporation, Mystic, Connecticut (Xomed, Jacksonville, Florida). Since the M-PACT Eye Drain 80cc, Eye Drain 400cc, Eye Wick 8-inch, and Surgical Spears are identical to product currently marketed by Merocel, the only changes will be in regard to labeling and packaging.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Barry Hale  
M-FACT Corp.  
1040 OCL Parkway  
Eudora, KS 66025

JUL 31 1997

Re: K971832  
Trade Name: Ivalon PVA Surgical Spear; Ivalon Eye Drain, 80cc; Ivalon Eye Drain,  
400cc; Ivalon Eye Wick  
Regulatory Class: II  
Product Code: 86 HOZ  
Dated: May 14, 1997  
Received: May 19, 1997

Dear Mr. Hale:

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 (Pre-market 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): K 971832

Device Name: Sponge, ophthalmic

INDICATIONS FOR USE:

The Ivalon® Eye Drain 80cc, Eye Drain 400cc, Surgical Spears, and Eye Wick 8-inch are used to absorb fluids from the operative field in ophthalmic surgery.

(Please do not write below this line - use another page if needed.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Ophthalmic Devices

510(k) Number K 971832

Prescription Use

OR

Over-The-Counter Use \_\_\_\_\_