DEC 21 1999

K993883

A - 510(k) SUMMARY OF SAFETY AND EFFICACY

DATE PREPARED:	November 2, 1999
SUBMITTER:	M-Pact Corp. 1040 OCL Parkway Eudora, KS 66025 PH: 785-542-2920 ext. 112 800-255-4152 Fax: 785-542-3608
CONTACT PERSON:	Al Boedeker, Manager of Regulatory Affairs And Quality Assurance.
TRADE (PROPRIETARY) NAME:	M-Pact Corneal Light Shield
COMMON NAME:	Corneal Light Shield
DEVICE CLASSIFICATION:	Class II
PREDICATE DEVICE:	Merocel -
DESCRIPTION OF DEVICE:	The M-Pact Corneal Light Shield is designed to be placed on the surface of the cornea during ophthalmic procedures to shield the retina from excessive illumination. The Corneal Light Shield is transient to minimal short-term use only. The Shield is nonabrasive, and is formulated to resist tearing or shedding of fibers.
STATEMENT OF INTENDED USE:	The Corneal Light Shield is a sterile sponge that is not absprbable by the body. It is intended for short-term transient use by a physician to be placed on the surface of the cornea and shield the retina from illumination during ophthalmic procedures. The Corneal Light Shield is to be used once and discarded.

TECHNOLOGICAL CHARACTERISTICS:

The M-Pact Corneal Light Shield has similar technological characteristics compared to the predicate device. The features are given in the Substantial Equivalence Table below.

SUBSTANTIAL EQUIVALENCE TABLE

FEATURES	M-pact Corneal Light Shield	Merocel Corneal Sponge
Made of PVA Sponge Bio-compatible and non-toxic	YES	YES
shields the retina from laser illumination	YES	YES
Foam is compressed and dried prior to packaging	YES	YES
Sterilized by Gamma or e-beam irradiation	YES	YES
Stored with moisture barrier packaging	YES	YES
Interconnected cell structure that prevents loose particles	YES	YES
Tear resistant	YES	YES
Nonabrasive	YES	YES
Absorbs about 15 times its weight in fluid	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1999

M-Pact Corporation
Mr. Al Boedeker
Manager of Regulatory Affairs
and Quality Assurance
1040 OCL Parkway
Eudora, KS 66025

Re: K993883
Trade Name: Corneal Light Shield (ophthalmic sponge)
Regulatory Class: II
Product Code: 86 HOZ
Dated: November 11, 1999
Received: November 15, 1999

Dear Mr. Boedeker:

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): K993883

Device Name: CORNEAL LIGHT SHEILD

INDICATIONS FOR USE:

The Corneal Light Shield is a sterile sponge that is not absorbable by the body. It is intended for short-term transient use by a physician to be placed on the surface of the cornea and shield the retina from illumination during ophthalmic procedures. The Corneal Light Shield is to be used once and discarded.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jan W. C. Brown, P.H.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K993883

Prescription Use X OR Over-The Counter

Prescription Use (Per 21 CER 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)