

REVISED 5/28/97

**Attachment 1  
510(k) Summary**

JUN - 4 1997

K971465

**National Healthcare Manufacturing Corp.  
Ophthalmic Kit or Tray**

**Submitter Information:**

Alice Gibson  
General Manager  
National Healthcare Manufacturing Corp.  
251 Sulteaux Crescent  
Winnipeg, Manitoba R3J 3C7  
Canada

**510(k) Summary Prepared by:**

Carolann Kotula  
Official Correspondent for NHMC  
c/o mdi Consultants, Inc.  
55 Northern Boulevard  
Great Neck, NY 11021

Phone: (516) 482-9001  
Fax: (516) 482-0186

**Date 510(k) Summary Prepared:** April 7, 1997

**Name/Classification of the Device:**

**Classification Name:** Surgical Procedure Packs

**Common Name:** Ophthalmic Pack, Tray, or Kit

**Attachment 1  
510(k) Summary**

**Proprietary Name:** National Medical Healthcare custom  
Ophthalmic kits or trays

**Classification:** A classification for these devices  
could not be located, however, the  
medical devices within the kits or trays  
are Class I and Class II devices

**Identification of the Legally Marketed Device to which the Submitter Claims  
Equivalence:**

The NHMC Custom **Ophthalmic packs** are substantially identical in materials,  
packaging, sterilization, and intended use to the Alcon Surgical Custom  
Ophthalmic Trays legally marketed under K880961.

**Description of the Subject Device:**

The National Healthcare Manufacturing custom ophthalmic procedure trays or kits  
are sterile , disposable , medical device convenience kits. National Healthcare  
Manufacturing Corporation currently markets these kit in Canada as: Cataract Pack,  
Ophthalmology Pack, and others. These kits are custom to the customer, whose  
specifies the type and quantity of the materials to be included in the kit. Please see  
attached list.

**Intended Use of the Subject Device:**

These kits are a convenience assemblage of medical devices intended for use by  
trained physicians for ophthalmic surgical procedures. National Healthcare  
Manufacturing Corporation does not cause or promote new intended uses for the  
devices within these kits.

**Technological Characteristics of the Subject Device:**

There are no differences in the characteristics of the subject device and the  
predicate.

Ophthalmology Pack

| Base material Number | Description                   | Quantity | Vendor |
|----------------------|-------------------------------|----------|--------|
| 17-888-001           | central 18 ga                 | 1        |        |
| 10-914-001           | lower cap                     | 2        |        |
| 11-328-009           | eye pad                       | 2        |        |
| 11-328-026           | eye shield clear              | 1        |        |
| 11-901-001           | gown nonya                    | 1        |        |
| 11-901-002           | gown w/ sterile back          | 1        |        |
| 12-252-009           | beaver blade 7516             | 1        |        |
| 12-441-001           | skin marker with tape         | 1        |        |
| 12-603-001           | medicines cup 30 ml           | 1        |        |
| 12-505-002           | medicines cup 60 ml           | 1        |        |
| 12-743-003           | needles 26 x 1/8              | 1        |        |
| 12-745-007           | needles 23 ga x 1             | 3        |        |
| 12-745-009           | needles 19 x 1 1/2"           | 1        |        |
| 12-745-012           | needles angled 19 ga          | 1        |        |
| 12-745-014           | needles 27 ga x 1/2"          | 1        |        |
| 12-745-015           | needles angled 27 ga          | 1        |        |
| 13-003-001           | label                         | 4        |        |
| 13-065-002           | lambio applicator             | 1        |        |
| 13-065-003           | cotton tipped applicator      | 20       |        |
| 13-789-001           | gauze 5 x 5 x 5/8"            | 5        |        |
| 13-789-006           | gauze 3x3 8 ply               | 5        |        |
| 13-789-007           | eye specur wrap roll          | 10       |        |
| 13-735-007           | Ziploc bag                    | 1        |        |
| 13-735-023           | 3 compartment tray            | 1        |        |
| 13-731-032           | hester bag 14 x 18            | 1        |        |
| 13-840-008           | eyrings 6 x 11                | 1        |        |
| 13-840-009           | eyrings 8 x 11                | 1        |        |
| 14-077-038           | absorbent towel               | 1        |        |
| 14-424-001           | Poly Bag                      | 1        |        |
| 16-013-002           | saline 50 ml                  | 1        |        |
| 16-013-011           | scholl's 100 joint 2 oz       | 1        |        |
| 16-045-002           | lag sponge 18 x 18            | 3        |        |
| 16-071-007           | sterilize cover 21 x 28       | 1        |        |
| 16-071-008           | sterilize cover 7 x 8 1/2     | 1        |        |
| 16-046-001           | back table cover 44 x 78      | 1        |        |
| 16-046-008           | eyro stand cover              | 1        |        |
| 19-848-023           | eyro stand 40 x 48 aperture   | 1        |        |
| 15-666-027           | striped 3/4 sheet             | 1        |        |
| 15-846-035           | foam chair                    | 1        |        |
| 18-874-001           | coverly lip 11 polar straight | 1        |        |



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 4 1997

Ms. Alice Gibson  
National Healthcare Manufacturing Corp.  
c/o Carolann Kotula  
MDI Consultants, Inc.  
55 Northern Blvd.  
Great Neck, NY 11021

Re: K971465  
Trade Name: Ophthalmic Pack/Tray/Kit  
Regulatory Class: II  
Product Code: 78 KXX, 86 HMX,  
86 HOY, 86 HNM, 86 HQR  
Dated: April 17, 1997  
Received: April 22, 1997

Dear Ms. Gibson:

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.

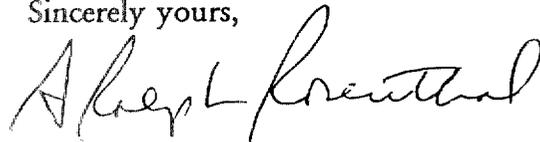
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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 at (301) 443-6597.

Sincerely yours,



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

Enclosure

NHMC Ophthalmic Kit or Tray  
Attachment 3

510(k) Number (if known) \_\_\_\_\_

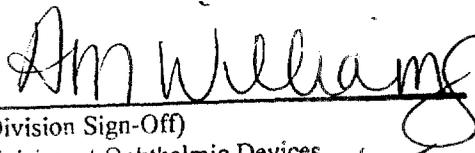
Device Name: National Healthcare Manufacturing Corporation Custom  
Ophthalmic Kit or Tray

Indications for Use: \_\_\_\_\_

These kits are a convenience assemblage of sterile, disposable, legally marketed medical devices intended for use by trained physicians for ophthalmic surgical procedures. National Healthcare Manufacturing Corporation does not cause or promote new intended uses for the devices within these kits.

(Please Do Not Write Below this Line/Continue on Another Page if Needed)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K971465

Prescription Use  OR Over the Counter Use \_\_\_\_\_  
(per 21 CFR 801.109)

(Optional Format 1-2-96)