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Attachment 1
510(k) Summary

K972013

P1072

National Healthcare Manufacturing Corp.
Ob/Gyn 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
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Date 510(k) Summary Prepared: May 8, 1997

Name/Classification of the Device:

Classification Name: Labor and Delivery Tray

Common Name: Ob/Gyn Procedure Pack, Tray, or Kit

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Attachment 1
510(k) Summary

Proprietary Name:	National Healthcare Manufacturing Corp. custom Ob/Gyn 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: Custom medical convienance kits or trays are commonly available to medical professionals and institutions. Baxter received marketing clearance for a "D & C Tray" under K901442. Medical Device Inspection Co., Inc. received approval to market a C-Section Tray Under K912017/B.

Comparative Information: The subject device and the predicates are substantially identical in materials, packaging, sterilization and intended use.

Description of the Subject Device: The NHMC custom Ob/Gyn procedure trays or kits are sterile , disposable , medical device convenience kits. NHMC currently markets these kit in Canada as Vaginal Delivery Pack, C Section 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.

Intended Use of the Subject Device: These kits are a convenience assemblage of medical devices intended for use by trained physicians for obstetrical and gynocological 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

National Healthcare Manufacturing Corporation
c/o Ms. Carolann Kotula
Vice President, RA/QA
mdi Consultants, Inc.
55 Northern Boulevard
Great Neck, New York, 11021

Re: K972013
National Medical Healthcare custom
Ob/Gyn kits, trays, or packs
Dated: May 28, 1997
Received: May 30, 1997
Regulatory class: II
21 CFR §884.4530/Product code: 85 KNA

AUG 26 1997

Dear Ms. Kotula:

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. However, you are responsible to determine that the medical devices you use as components in the kit/tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual 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. 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used in the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.

2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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,

Robert R Rathing /

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972013

Device Name: NHMC Custom Ob/Gyn Pack

Indications for Use:

This kits are a convenience assemblage of sterile, disposable medical devices intended for use by trained physicians for various gynocological and obstetrical procedures. See the attached list of "Obstetrical and Gynecological Devices".

NHMC 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)

Robert R Sattler
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K97 2013

Prescription Use ✓ OR Over the Counter Use ____
(per 21 CFR 801.109)

Obstetrical and Gynecological Convenience Kits or Packs

Amniocentesis Tray
Breast Pump Kit
Cervical Smear Kit
Cesarean Section Tray
Circumcision Tray
Culdocentesis Kit
Cytology Kit
D and C Tray
Delivery Kit
Emergency Obstetrical Kit
Endometrial Sampling Kit
Fetal Blood Sampling Kit (Excludes HIV testing)
Forensic Evidence Sexual Assault Kit
Gynecological Laparoscopic Kit
Labor and Delivery Kit
Maternity Kit
Obstetrical Kit
Obstetrical Anesthesia Kit
Obstetrical Vacuum Delivery Kit
Pap Smear Kit
Paracervical Anesthesia Kit
Seminal Fluid Collection Kit
Trocar Kit
Vaginal Examination Tray
Vasovasostomy Set

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972013

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____