MEDIPACK MEDICAL PACKAGING MFG. CO.
Lin-Kuo 4th Industrial Park. No. 13, Tin Hu Road,
Guei-Shan Hsiang, Tao-Yuan Hsien, 333 Taiwan.
E-Mail Address: medipack@ms13.hinet.net
Mfg@medipack.com.tw
http://www.medipack.com.tw
TEL: 886-3-3275678 FAX: 886-3-3276699, 3273388

ISO9002-EN46002 CERTIFIED FACTORY

K993764

DEC 16 1999

3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:

Medipack Medical Packaging Manufacturing Co.
Lin-Kuo 4th Industrial Park
No. 13, Tin Hu Road
Guei-Shan Hsiang
Tao-Yuan Hsien
333 Taiwan

Tel: 886-3-327-5678
Fax: 886-3-327-5599
medipack@ms13.hinet.net

B. ESTABLISHMENT REGISTRATION NUMBER: 9880261

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854

Tel. : (301) 519-1098
Fax : (301) 519-1389

D. DATE OF PREPARATION OF THIS SUMMARY: November 4, 1999

E. PROPRIETARY (TRADE) NAME: **MEDIPACK® SEE-THROUGH SELF SEAL STERILIZATION POUCH**

010015

F.	**COMMON NAME:**	Sterilization Pouch
G.	**CLASSIFICATION NAME:**	Pack, Sterilization Wrapper, Bag and Accessories
H.	**PROPOSED REGULATORY CLASS :**	Class II
I.	**DEVICE PRODUCT CODE:**	KCT
J.	**REFERENCE:**	21CFR par.880.6850
K.	**PANEL:**	General Hospital

L. DESCRIPTION:

The **MEDIPACK® SEE-THROUGH SELF SEAL STERILIZATION POUCH** is a device composed of medical paper. It is a bleached wet strength paper conforming to recognized material standards and can be sterilized by steam, ethylene oxide gas and irradiation.

M. INDICATIONS FOR USE:

The **MEDIPACK® SEE-THROUGH SELF SEAL STERILIZATION POUCH** is intended to be used to enclose another medical device that is to be sterilized by a health provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

N. PREDICATE DEVICE:

The **MEDIPACK® SEE-THROUGH SELF SEAL STERILIZATION POUCH** is substantially equivalent to the Global Healthcare Self-Sealing Sterilization Pouch (K990567) and the Defend Self-Sealing Sterilization Pouch (K932056).

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the The **MEDIPACK® SEE-THROUGH SELF SEAL STERILIZATION POUCH** and the predicate devices have the same intended use and all are composed of the identical materials and have identical Indications for Use. All are produced by the same manufacturer!

P. SUMMARY OF STUDIES:

Since the manufacturer, Medipack Medical Corporation, produces the identical product for the Global Healthcare and Carl Parker Associates (Defend Self-sealing Pouch), all specifications and test results are applicable to each as well as to the **MEDIPACK® SEE-THROUGH SELF SEAL STERILIZATION POUCH**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1999

Medipack - Medical Packing Manufacturing Co.
c/o Mr. Norman F. Estrin
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854

Re: K993764
Trade Name: Medipack® See-Through Self Seal Sterilization Pouch
Regulatory Class: II
Product Code: KCT
Dated: November 4, 1999
Received: November 8, 1999

Dear Mr. Estrin:

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.

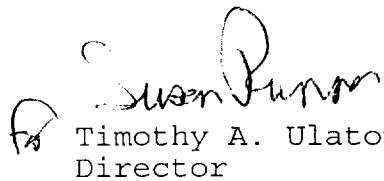
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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) 594-4692. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **MEDIPACK® SEE-THROUGH SELF SEAL STERILIZATION POUCH**

Indications for Use:

The **MEDIPACK® SEE-THROUGH SELF SEAL STERILIZATION POUCH** is intended to be used to enclose another medical device that is to be sterilized by a health provider by steam or ethylene oxide (EtO). It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-the-Counter Use X

(Optional Format 1-2-96)

Alice S. Lin

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K992764