510 (k) SUMMARY

FEB 0 5 2002

➢ Applicant	: HS Hospital Service S.p.A. Via Naro,81 – 00040 Pomezia (Rome) Italy
➢ Contact Person	: MMC International, LLC Mr. Lucio Improta 10147 Umberland Place – Boca Raton, FL 33428 Tel. (561)477-1671 - Fax. (561)477-0863 e-mail : mmcintern@aol.com
➢ Submission Date	: October 27, 2001
➢ Trade Name	: TrapSystem® Set Bone Marrow Biopsy Needle
➢ Common Name	: Bone Marrow Biopsy Needle
➢ Classification Name	➢ : 876.1075 - Biopsy instrument

❖ **Indication for use :**

This biopsy instrument is used for drawing of osteomedullary substance and or for explantation of bone marrow.

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SECTION I - PRODUCT NAME/DESCRIPTION

A. Trade Name — TrapSystem® Set Bone Marrow Biopsy Needle

B. Usual Name — : Bone Marrow Biopsy Needle

C. Description — : A disposable single use Biopsy Needle

1. Intended Use — : This biopsy instrument is intended to be used for drawing osteomedullary substances and or explantation of bone marrow.

2. Material — The product consist of a 304 stainless steel cannula and 302 stainless steel stylet.
The cannula is inserted molded into an ABS hub that provide a grip for manipulation of the Needle.
Inside of the cannula is a stylet made by 302 stainless steel, inserted molded into an ABS hub
An additional patented stylet is provided to be used for trapping the sample in the cannula
An extracting 302 stainless steel wire with safety grip.
The protective cover of cannula is made of polypropilene

This type of device is also referred to Promedical Ltd, PRO-B biopsy Needle 510 (k) # K952350

We will incorporate all these features into our product, therefore providing the physician with a product that will safety assist them in their operation.

A listing of needle dimension is included in Section I – Attachment C

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Section I - Attachment C

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TABLE OF DIMENSION

Code	*Description*
TRAPJ 1305	13G x 50mm
TRAPJ 1306	13G x 65mm
TRAPJ 1310	13G x 100mm
TRAPJ 1315	13G x 150mm
TRAPJ 1205	12G x 50mm
TRAPJ 1210	12G x 100mm
TRAPJ 1215	12G x 150mm
TRAPJ 1105	11G x 50mm
TRAPJ 1110	11G x 100mm
TRAPJ 1115	11G x 150mm
TRAPJ 1005	10G x 50mm
TRAPJ 1010	10G x 100mm
TRAPJ 1015	10G x 150mm
TRAPJ 0905	9G x 50mm
TRAPJ 0910	9G x 100mm
TRAPJ 0915	9G x 150mm
TRAPJ 0805	8G x 50mm
TRAPJ 0810	8G x 100mm
TRAPJ 0815	8G x 150mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2002

Lucio Improta
MMC International, LLC
10147 Umberland Place
Boca Raton, Florida 33428

Re: K013692
Trade Name: TrapSystem® Set Bone Marrow Biopsy Needle
Regulation Number: 876.1075
Regulation Name: Gastroenterology/Urology Biopsy Instrument
Regulatory Class: II
Product Code: KNW
Dated: October 27, 2001
Received: November 7, 2001

Dear Mr. Improta:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) # K013692

DEVICE NAME

TrapSystem® Set
Bone Marrow Biopsy Needle

INDICATION FOR USE

This biopsy instrument is used for drawing of osteomedullary substance and or for explantation of bone marrow

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013692

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)