510 (k) SUMMARY

DEC 1 2 2001 K013069

Applicant : **H.S. Hospital Service S.p.A.**
Via Naro, 81 – 00040 Pomezia (Roma) 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 : **September 03, 2001**

Trade Name : **BIOSPEED™ Spring Loaded Biopsy Needle**

Common Name : **Spring Loaded Biopsy Needle**

Classification Name : **876.1075 - Biopsy instrument**

Substantial Equivalence :

Company Name	Product Name	510(k) #
Promedical Ltd	PRO-B Biopsy Needle	K951598

Indication for use :
This biopsy device can be used in Fluoroscopic, CT, Mammographic and Laparoscopic procedures to obtain biopsies of various tissues including those from Breast, Kidney, Liver, Prostate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2001

H.S. Hospital Service S.p.A.
c/o Mr. Lucio Improta
MMC International, LLC
10147 Umberland Place
Boca Raton, Florida 33428

Re: K013069
Trade/Device Name: BIOSPEED™ Spring Loaded Biopsy Needle
Regulation Number: 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: September 3, 2001
Received: September 13, 2001

Dear Mr. Improta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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,

Susan Walker, 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) # K013069

DEVICE NAME **BIOSPEED™ Biopsy Needle**

INDICATION FOR USE

This device is an automated, disposable biopsy needle and can be used in Fluoroscopic, CT and Mammographic procedures to obtain biopsies of various tissues including those from Prostate Kidney, Breast and Liver.

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 General, Restorative
and Neurological Devices

510(k) Number K013069

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