K000581

FEB 2 3 2001

Premarket Notification 510 (k) Summary

Applicant: Naonori Maeda
Maeda Toyokichi Shoten
Address; 2-8-28, Shoan, Suginami-ku, Tokyo,167-0054, Japan
Phone; 81-03-3332-7634
Fax; 81-03-3332-8117

Contact person: Yoichi Kamada
Address; 613-110, Ohzenji, Asao-ku, Kawasaki, 215-0013, Japan
Phone and Fax; 81-044-966-0496

Trade Name: "Maeda" New Needle Disposable

Common Name: Acupuncture Needle

Established Registration Number: N.A.

Classification Panel: 80

Procode: MQX

Class: II

Purpose of the Submission: new

Sterilizing Site: Radia Industry Co. Ltd.,
168, Ohyagi-cho, Takasaki-shi, Gunma-ken

Description of the Device and Intended Use:

Maeda acupuncture needles, are devices intended to pierce the skin in the practice of acupuncture by qualified practitioners.

Maeda acupuncture needles, sterilized and disposable, have been in the Japanese market for about 40 years after obtaining the approval of Minister of Health and Welfare, and have been offering great safety without any serious or life threatening accidents.

Device Specifications are described in detail in Pre-market Notification Submission. They are very common and similar to other acupuncture needles.

Comparison to a legally marketed Device:

Maeda Acupuncture Needles are equivalent to "Seirin PYONEX Acupuncture Needles" which have been in the U.S. market for a few years. Their Pre-

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Market Notification 510(k) Number is K970254. The similarities and differences between Maeda Needles and Seirin Needles are described in detail in our Pre-Market Notification Submission.

In conclusion, based on the information provided with this 510(k) application, Maeda Acupuncture Needles with the trade name of "Maeda New Needle Disposable" meet the criteria for 510(k) acceptance.

前田直則

Naonori Maeda
President
Maeda Toyokichi Shoten

Date: February 16 ,2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2001

Maeda Toyokichi Shoten
C/O Mr. E.J. Smith
Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

Re: K000581
Trade Name: Maeda New Needle Disposable
Regulatory Class: II
Product Code: MQX
Dated: December 10, 2000
Received: December 11, 2000

Dear Mr. Smith:

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 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). 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 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, 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

K000581

510(k) Number (if known): K000581

Device Name: Maeda New Needle Disposable

Classification Panel: MQX

Indications for Use:

Acupuncture Needles are intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

Tatiana Cucciola

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000581