K030190

Carbo Trading Co. Inc.

4500 Sheppard Avenue East, Unit 1
Toronto, ON. M1S 3R6
Phone: (416) 299-6643 Fax: (416) 299-7003 Toll-Free: 1-800-370-9077
www.carbotrading.com

FEB 21 2003

January 16, 2003

PREMARKET NOTIFICATION [510(K)] SUMMARY

[As required by CFR 21 807.92(c)]

Submitter:

Suzhou Sen Sen Medical Supplies Limited
Wu Xian New Development Zone
38 Shi Hu Road East
Suzhou, Jiangsu. 215128
China
Tel: (86) (512) 6564-5122
Fax: (86) (512) 6528-4420

Applicant:

Kevin Liu
Carbo Trading Co. Inc.
4500 Sheppard Avenue East
Unit #1
Scarborough, ON. M1S 3R6
Canada
Tel: (416) 299-6643
Fax: (416) 299-7003

Device Summary (a)(2):

Trade Name:	Carbo/Optimed brand Acupuncture Needle
Common or Usual Name:	Acupuncture Needle
Classification Name:	Acupuncture Needle, Single Use
Medical Speciality:	General Hospital
Device Class	II
Product Code:	MQX
Regulation Number:	880.5580

Substantial Equivalence (a)(3):

Carbo/Optimed brand acupuncture needle is substantially equivalent to acupuncture needles sold in the US market. It's design and intended use is SE to the following brand of acupuncture needles available in the US market:

Tai-Chi Acupuncture needles	(K003760)
Addiquip Acupuncture needles	(K981272)

..... *continued on next page*

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Description (a)(4):
Carbo/Optimed brand acupuncture needles are sterile disposable needle for one time use only. The needle shaft/body is made of surgical grade stainless steel (as per ASTM specifications) and is used for the practice of acupuncture as determined by state. The handle is made of aluminium alloy, which does not enter the human body, but is used to control the insertion of the needle.

Intended Use (a)(5):
Carbo/Optimed brand acupuncture needles are intended to be used to pierce the skin in the practice of acupuncture (by qualified practitioner of acupuncture) as determined by the States.

Technological Characteristics (a)(6):
A Carbo/Optimed brand acupuncture needle has the same technological characteristics as the predicated devices described in paragraph (a)(3). Carbo/Optimed brand needles also comes in bulk packaging with 5 needles in one tube with a total of 500 needles per box, which is SE to Tai-Chi Acupuncture needles (K003760).

Assessment and Performance Data (b)(1)(2)(3):
Substantial equivalence is not based on an assessment of performance data.

Kevin Liu, Sales Manager — January 16, 2002 Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

Suzhou Sen Sen Medical Supplies Limited
C/O Mr. Kevin Liu
Carbo Trading Company, Incorporated
4500 Sheppard Avenue East, Unit #1
Scarborough, Ontario M1S 3R6
CANADA

Re: K030190
Trade/Device Name: Carbo/Optimed Brand Acupuncture Needle
Regulation Number: 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: January 16, 2003
Received: January 21, 2003

Dear Mr. Liu:

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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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 Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use Statement

This device is intended to pierce skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030190