

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)

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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):**

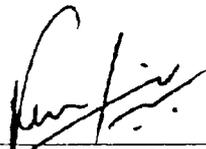
Carbo/Optimed brand acupuncture needles are intended to be used to pierce the skin in the practice of acupuncture (by qualified practitioner of acupuncture) as determined by the States.

### **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



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,

A handwritten signature in black ink that reads "Susan Runner". The signature is written in a cursive style with a large, looped initial "S".

Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

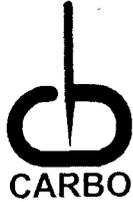
Office of Device Evaluation

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.

*Rafaela Cuervo*

(Division Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K030190