K041465

JUL 2 3 2004

SINON CORPORATION

23, Sec. 1, Mei Chuan W.Road, Taichung 403, Taiwan
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" 510(k) SUMMARY "

Submitter's Name: *SINON Corporation*
No. 23, Sec. 1, Mei Chuan W. Road, Taichung, Taiwan, 403, ROC

Date summary prepared: May 28, 2004

Device Name:

Proprietary Name:	SINON SN-L402 Lightweight Wheelchair
Common or Usual Name:	Mechanical Wheelchair
Classification Name:	Mechanical Wheelchair, Class I, 21 CFR 890.3850

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The SINON SN-L402 Foldable Wheelchair is an indoor / outdoor wheelchair that has a base with four-wheeled with a seat. The device can be disassembled for transport and it is foldable easily. The device uses a standard sling type back and seat, the upholstery fabric meets the California Technical Bulletin CAL 117 standard for flame retardant.

Performance Testing:

SN-L402 Lightweight Wheelchair meet the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 and ISO 7176 Wheelchair Standards.

Legally marketed device for substantial equivalence comparison:

BIOTECH B900 SUPER LIGHT Wheelchair (**K020472**).

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C.2 COMPARISON SUMMARY

(We place the related information for the predicate device in the following pages.)

The new device SN-L402 and predicate device BIOTECH B900 have the same intended use, and the weight limit **100kgs** between the two devices is the same. Mainframes of two devices are foldable. The overall dimensions are similar. Back upholstery material is also the same resistance-ignitability fabric. **The major differences existing are the overall dimension, and the size of tires are differences between the two devices.** The overall appearance differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.

The seat heights between the new device and the predicate device have small difference, not leading to any safety hazard. The hanger and rear axle designs are same. The weights of the two devices are similar. At last the optional accessories for the new device are more than those of the predicate one, and the users have more adversity to choose the needed accessories to accommodate their needs.

Based on the above the information and the analysis, we know that the new device and the predicate device have the same technological aspects and the same intended use, except for tiny appearance differences. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

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Summary for substantial equivalence comparison:

The new device and the predicate device have the same intended use and the weight limit **100kgs** between the two devices is the same. Mainframes of two devices are foldable. The overall dimensions are similar. Back upholstery material is also the same resistance ignitability fabric. The major differences existing of the two Mechanical Wheelchairs are the different overall dimension and weight between the two devices. The overall appearance and weight differences are not safety aspect. So the new device is substantially equivalent to the predicate devices in this aspect.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Sinon Corporation
C/o Dr. Ke-Min Jen
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, China (Taiwan) 300

Re: K041465
Trade/Device Name: SINON SN-L402 Lightweight Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: May 28, 2004
Received: June 2, 2004

Dear Dr. Jen:

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) 594-4659. 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,

for Mark N. Melkerson

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) NUMBER (IF KNOW): TBA

DEVICE NAME: *SINON SN-L402 Lightweight Wheelchair*

INDICATIONS FOR USE:

The device is intended for medical purposes to provide mobility to person restricted to a sitting position.

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

510(k) Number K041465

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)