WELL SUCCESS BIOTECH. INC.
6F, No.70, Zi You Road, Hsinchu City, 300, Taiwan, R.O.C.
TEL : 886-3-5357667 FAX : 886-3-5357669
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K041187

MAY 25 2004

" 510(k) SUMMARY "

Submitter's Name: **WELL SUCCESS Biotech. Inc.**
6F, No.70, Zi You Road, Hsinchu City, 300, Taiwan, R.O.C.

Date summary prepared: May 1, 2004

Device Name:

Proprietary Name:	A&I Scooter, SC-301
	(Trade name: A&I, A&E, J&C)
Common or Usual Name:	Electrical Scooter
Classification Name:	Motorized 3-Wheeled Vehicle, Class II, 21 CFR 890.3800

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 A&I Scooter SC-301 is an indoor / outdoor Powered Scooter that is battery operated. It has a base with four-wheeled with a seat. The movement of the Scooter is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically Powered Scooters, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

WU's 3-Wheeled Neo Scooter, WT-T3D **(K032488)**

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C.2 COMPARISON SUMMARY

(We place the related information for the predicate device in the following pages, including the visual appearance, 510k information on the FDA website, and the comparison and summary table.)

The intended uses, back upholstery, maximum speed, and warranty period between the new device SC-301 and the predicate device WT-T3D are all the same. Especially the electronic systems between two devices are the same suppliers and all passed by the UL certificated including the batteries and recharge, and the electronic controllers between the two devices are also passed by the UL certificated. Besides, the back upholstery is the same material, and also passed the resistance ignition test by SGS. Thus the same safety level for the two devices is assured.

The major difference existing for new device is more agile and easy to fold for storage or transportation and the predicate device is for general use. So the sizes and visual appearance among them have differences, and there is no safety level difference.

To sum up, the overall dimension, the size of tires, and the weight 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.

Based on the above the information and the analysis, we know that the subject device and the predicate devices have the same intended use, the same technological aspects and only minor dimensions or data differences exist. 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 electronic systems between the two devices are all passed by the UL certificated, including the electronic controllers, the batteries and recharge. Besides, the two devices are the same maximum speed and back upholstery. Thus the same safety level for the two devices is assured. The major differences existing of the two Powered Scooters 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

MAY 25 2004

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

Re: K041187
Trade/Device Name: A & I Scooter, SC-301
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: May 1, 2004
Received: May 6, 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: *A&I Scooter, SC-301*

INDICATIONS FOR USE:

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

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)

for Mark N Millar

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

510(k) Number K041187