



SEP - 8 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steve Gibson
Specmat Technologies, Inc.
215 Dunavant Drive
Rockford, Tennessee 37853

Re: K042304
Trade/Device Name: Chunc Junior Model# Sm 242, Chunc Adapt Model # Sm 251
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: August 24, 2004
Received: August 25, 2004

Dear Mr. Gibson:

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.

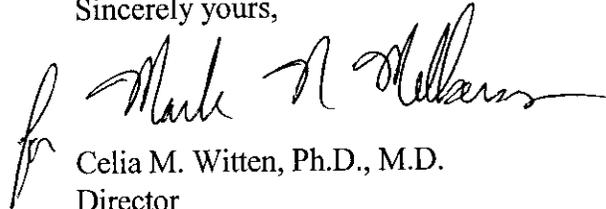
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish at the end.

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

Indications for Use

510(k) Number (if known): K042304

Device Name: Chunc Junior Model# Sm 242, Chunc Adapt Model # Sm 251

Indications For Use:

Chunc pediatric attendant controlled wheelchair is intended for clients with moderate to specialist needs and has been designed with the occupants and attendants needs first and foremost.

Chunc manual wheelchairs empower physically challenged persons by providing a means of mobility. This includes temporary and permanent conditions such as:

Arthritis	Tetraplegic	Multiple Sclerosis
Amputee	Quadriplegic	Polio
Paraplegic	Spina Bifida	Cerebral Palsy
Muscular Dystrophy	and any other immobilizing or debilitating condition	

The modular design of the wheelchair chassis, frame and seating allows for flexibility and ease of modification to suit postural, functional and social needs. This coupled with material choice and the frequent use of like parts across the wheelchair have enabled us to keep costs at a minimum. Attendant functions have been designed to be easily identifiable from engineer functions using unified adjustments with color coding which are also simple to use and maintain. By moving away from the cumbersome welded steel structures of conventional wheelchairs we have been able to utilize a selection of materials and manufacturing techniques to ensure the wheelchair is lightweight and therefore comfortable to use. Chunc is currently manufactured and marketed in the UK and has been approved by the National Health Service (NHS) and has the relevant CE marking. Chunc also provides the ability for Bus Transportation and motor vehicle transportation with the use of wheelchair tiedown and occupant restraints systems (WTORS) that meet the requirements of SAE J2249

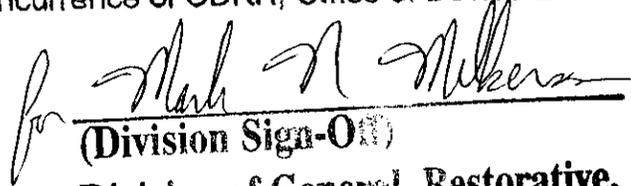
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use YES
(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)


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

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