K040754

JUL 2 3 2004

AMERICAN BANTEX CORPORATION

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Tracy S. Best, Regulatory Affairs Consultant
Preparation Date: July 10, 2004

Summary of Safety and Effectiveness for the:

Trade Name: American Bantex MS 4, Mini Scooter

Common Name: Scooter, 4-wheeled, Powered

Classification Number & Name: 89 INI (890.3800) Vehicle, Motorized 3-Wheeled

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Legally Marketed Predicate Devices for Substantial Equivalence:

*Mega Motion, Inc. – Mega 4 Scooter, K982144

Rationale for SE: The Mega Motion, Mega 4 is a Class II device that is intended to provide assistance and help people lead a more productive and mobile lifestyle. The 4-wheeled scooter provides a stable ride while the two forward wheels steer the scooter. Mega 4 us an outdoor and indoor product that is capable of traveling on bumpy or uneven terrain. The pneumatic tires and sealed transaxle contribute to the quiet operation of the scooter. The Mega 4 has a built-in charger that plugs into a standard 110-120V~ outlet. The dynamic regenerative brake (electric motor) and secondary parking brake are redundant to one another.

Description of Submitted Device:

The American Bantex MS 4 Mini Scooter is a Class II device that also is intended to provide assistance to individuals that are unable to walk long distances. The rear-wheel drive and two wheel steering abilities allow the user to effortlessly control this device. The body (shell) is made of rigid Acrylonitrile-Butadiene-Styrene Copolymer. The shell is available to the consumer in two colors. The variable speed dial on the tiller column enables users single-handed operation while moving forward. The sealed (24 V) transaxle motor is quiet to operate. As with the predicate device, the MS 4 breaks-down into several components for easy, tool less assembly, disassembly and transportation. The MS 4 is substantially equivalent in safety, efficacy, technology, and intended use to the Mega 4, marketed by Mega Motions, Inc.

American Bantex affirms that we contract with a fully operational quality manufacturing system, which conforms to the QSR requirements of 21 CFR Part 820, as well as the Quality elements of the European Medical Device Directive, 93/42/EEC for CE Marking. Design History Files are maintained for the development and distribution of products and devices and they are tested using *Independent Testing Services* prior to marketing them.

Intended Uses of the American Bantex MS 4:

The American Bantex 4 wheeled, MS4 Mini Scooter, has been designed to help people who have a difficult time walking. The user must have use of hand and upper-body mobility. People who have some mobility, but cannot walk for long distances or people that may need crutches to walk will generally purchase this scooter. The MS4 Mini scooter is designed for both indoor and outdoor use in clean and dry conditions.

Technological Characteristics and Substantial Equivalence:

Table 1: Comparison of American Bantex MS 4 to the predicate Mega Motions, Mega 4 Scooter.

Component:	American Bantex MS 4	Mega Motions, Mega 4
Length	119 cm / 48 inches	119 cm
Width	61 cm / 24 inches	24 inches
Turning Radius	107 cm / 42 inches	42 inches
Maximum Speed	8 Km/h / 5 M/h	5 M/h
Weight Capacity	120 Kgs / 264 Lbs	114 Kgs / 264 Lbs
Maximum Range	32-40 Km / 17-21 Miles	20-25 Miles
Battery Type	2, 12V 32 AH Lead Acid sealed	2, 12 V 31 AH Lead Acid sealed
Brakes	Regenerative and Electromechanical	Regenerative and Electromechanical
Battery Charger	On-board, plug in	On-board
510(k) File Number	Pending this Application	K982144

The characteristics, methods of operation, accessories and indication for use are all equivalent to that of the predicate device. The evaluation and performance verification included performance testing in accordance with ANSI / RESNA WC/Vol. 2-1998, Section 21, Requirements and test methods for electromagnetic compatibility of powered wheelchairs and motorized scooters. The results of such testing as well as, certifications from upholstery testing, functional performance testing, stability (ISO 7176-1 & -2) and electrical immunity testing required by the FDA and European Agencies are included in this submission. The battery charger provided is non-medical grade, for home use only.

Conclusion:

The successful testing and comparison has demonstrated the device consistently performed within its design parameters, is as safe and effective, and performs as well as, or better than, the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Mr. Tracy S. Best
American Bantex Corporation
994 North Main St.
Bountiful, Utah 84010

Re: K040754
Trade/Device Name: MS 4 Mini Scooter
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Codes: INI
Dated: July 10, 2004
Received: July 13, 2004

Dear Mr. Best:

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 Celia M. Witten, PhD, MD
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):

Device Name: MS 4 Mini Scooter

Indications for Use:

The MS 4 Mini Scooter has been designed to help people who have a difficult time walking. The user must have use of hands and upper-body mobility.

People who have some mobility, but cannot walk for long distances or people that may need crutches to walk will generally purchase this scooter.

The MS 4 Mini Scooter is designed for both indoor and limited outdoor use in clean and dry conditions.

Prescription Use __X__ 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 Milhous

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

510(k) Number K040754