SPECIAL 510(K) SUMMARY FOR THE MODIFICATION TO INVACARE'S MODEL 9000 BARIATRIC MANUAL WHEELCHAIR (TOPAZ)

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is K060582.

Date: March 6, 2006

Submitted by: Invacare Corporation
One Invacare Way
Elyria, Ohio 44035-4190

Telephone: 440-329-6356
Fax: 440-326-3607

Contact Person: Mr. Carroll Martin

Trade Name: Topaz

Common Name: Manual Wheelchair

Classification Name: Wheelchair, mechanical per 21 CFR Section 890.3850

Legally Marketed Predicate Device(s): Invacare Model 9000 Bariatric Wheelchair K002317, August 25, 2000

Device Description: The Invacare Model 9000 Bariatric Manual Wheelchair (Topaz) is a manually operated, user propelled mechanical wheelchair. Its intended function and use is to provide mobility to persons limited to a sitting position. The wheelchair consists primarily of a steel frame, large rear wheels with hand rims for propelling the wheelchair, and smaller front pivoting casters for steering and turning. It is a folding, or non-rigid type of wheelchair that is designed for use by patients weighing up to 1000 lbs.

The frame is constructed of round, steel tubing that is welded. The tubing is 1" outside diameter (O.D.) with a wall thickness of 1/8". The seat width ranges from a minimum of 28" wide to a maximum of 30" wide and seat to floor height ranges from 17½" to 19½". The modification to this device consists of a frame with a reinforced design to withstand the higher weight capacity of 1000 lbs. In particular, two extra gussets have been added to the frontal tube and thicker gussets have been added to the rear upright and head tube. Also, the armrests have been reinforced and a stronger tire is used on the front caster.

INVACARE CORPORATION

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Intended Use: The intended use of the modified Invacare Topaz Bariatric Manual Wheelchair (Topaz) is to provide mobility to persons that may be restricted to a sitting position.

Substantial Equivalence: The modified Topaz is substantially equivalent to the Invacare Model 9000 Bariatric Manual Wheelchair, cleared on August 25, 2000 under 510(K) Accession Number K002317. It is a modification of the Model 9000 Bariatric Manual Wheelchair. The modifications consist of a frame with a reinforced design to withstand the higher weight capacity of 1000 lbs. In particular, two extra gussets have been added to the frontal tube and thicker gussets have been added to the rear upright and head tube. Also, the armrests have been reinforced and a stronger tire is used on the front caster.

The intended use of providing mobility to persons restricted to a sitting position and the functionality of the device, i.e. manual operation, remain the same. The major difference between the two devices and the subject of this Special 510(k) is that the Invacare Model 9000 Bariatric Manual Wheelchair has a weight capacity of 700 pounds. This modification is intended to allow the weight capacity of the wheelchair to increase to 1000 pounds.

Performance Testing: The performance testing conducted as a result of the modifications to the Invacare Model 9000 Bariatric Manual Wheelchair (Topaz), as required by the risk analysis, were performed and the results demonstrated that the predetermined acceptance criteria were met.

Performance Standards: Although no performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for mechanical wheelchairs, Invacare has tested the modifications to the Invacare Model 9000 Bariatric Manual Wheelchair (Topaz) in accordance with ISO 7176, parts 1 and 8.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Invacare Corporation
c/o Mr. Carroll Martin
One Invacare Way
Elyria, Ohio 44035-4190

Re: K060582
Trade/Device Name: Invacare Topaz Bariatric Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: March 6, 2006
Received: March 8, 2006

Dear Mr. Martin:

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 (240) 276-0120. 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
Acting 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: Invacare Topaz Bariatric Manual Wheelchair

Indications for Use: The intended use of the Invacare Topaz Bariatric Manual Wheelchair is to provide mobility to persons that may be restricted to a sitting position.

Prescription Use _____ AND/OR Over-The-Counter Use X
(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)

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

510(k) Number K060582