

MAY 23 2006



510(k) Summary
Nova Ortho-Med, Inc.
7000 Series Lightweight Wheelchairs

Submitter's Name and Address

Nova Ortho-Med, Inc.
P.O. Box 3039
Gardena, CA 90247
Phone: (310) 352-3600
Fax: (310) 352-3610

Physical Address Location:
1470 Beachey Place
Carson, CA 90746

Contact Person: Sue Chen President, CEO
Nova Ortho-Med, Inc.

Date Prepared: October 10, 2005

Name of Device and Proprietary Name:
7000 Series Lightweight Wheelchairs

Common or Usual Name: Manual Wheelchair

Classification Name: Wheelchair, Mechanical

Product Code: IOR

Regulation Number: 890.3850

Regulatory Class: Class 1

Comparison to Predicate Devices:

The 7000 Series Lightweight Wheelchair is substantially equivalent to the Invacare 9000 Series Wheelchair (K881951)

Device Description:

The 7000 Series Lightweight Wheelchair is mechanical wheelchair that is lightweight in design (weighs 31.5 lbs) and provides mobility to persons with limited mobility or persons limited to a sitting position. The 7000 Series Lightweight Wheelchair comes in 16", 18" and 20" seat widths and has component adjustments for optimum fitting. The 7000 Series Lightweight Wheelchair has dual crossbar support, flip back removable arms, flame retardant nylon upholstery, removable footrests with heel loops, dual axle positioning and wheel locks.

Intended Use:

The intended use of the 7000 Series Lightweight Wheelchair is to provide mobility to adult persons with limited mobility or adult persons limited to a seated position. The target population for the 7000 Series Lightweight Wheelchair is the United States adult population.

Non-Clinical Testing:

ISO 7176-16: Resistance to Ignition of Upholstered Parts - California Technical Bulletin 117 – Flammability Testing: Passed

ISO 1421: Upholstery Strength Test

Nova Orthopedic and Rehabilitation Appliance Inc. – The On Road Test for Durability: Test Date – March 16 – 25, 2005

- Running Speed: 60 rpm - Weight Load: 163 kgf
- Motion Test and Brakes Test - passed
- Static, Impact and Strength Test – passed

ISO 7176-11: Test Dummies

ISO 7176-13: Determination of Coefficient of Friction of Test Surfaces

ISO 7176: Determine of Effectiveness of Brakes

ISO 7176-15: Requirements for information disclosure, documentation and labeling.

ISO 7176-1: Determination of Static Stability

ISO WC: Determination of Overall Dimensions, Mass and Turning Space

Discussion of Clinical Testing Performed:

N/A

Conclusions:

The 7000 Series Lightweight Wheelchair has the same intended use and similar technological characteristics as the Invacare 9000 Series Wheelchair (K881951). All non-clinical testing and the predicate comparisons show that there are no safety or effectiveness issues or claims that differ from the predicate device cited. This submission complies with the requirements as stated in 21 CFR Part 807 Subpart E, that a new device is substantially equivalent to a predicate device in 21 CFR 890.3850. The conclusion is that the 7000 Series Lightweight Wheelchair is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2006

Nova Ortho-Med, Inc.
% Mr. Daniel W. Lehtonen
Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Road
Unit B7
Twinsburg, Ohio 44087

Re: K061273

Trade/Device Name: 7000 Series Lightweight Wheelchairs

Regulation Number: 21 CFR 890.3850

Regulation Name: Mechanical Wheelchair

Regulatory Class: I

Product Code: IOR

Dated: May 5, 2006

Received: May 8, 2006

Dear Mr. Lehtonen:

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

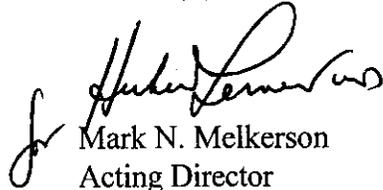
Page 2 - Mr. Daniel W. Lehtonen

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,



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) K061273

Device Name: **7000 Series Lightweight Wheelchair**

Indications for Use:

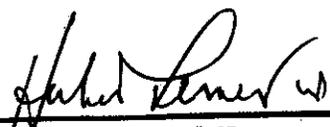
The intended use of the 7000 Series Lightweight Wheelchair is to provide mobility to adult persons with limited mobility or adult persons limited to a seated position. The target population for the 7000 Series Lightweight Wheelchair is the United States adult population.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K061273