SEP 0 9 2008

K08 2246

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1889 and 21 CFR 807.92.

510(k) Number _____ Date Prepared: July 30, 2008

Submitter's Name, Address and Contact Person

Dignity Medical Devices, Inc.
17500 29th Ave. North
Minneapolis, Minnesota 55447

Contact Person: Charmaine Sutton

Trade Name: Dignity 100

Common Name: Manual Wheelchair

Classification Name: Wheelchair, mechanical

Predicate Device
The Dignity 100 wheelchair is substantially equivalent to the Sunrise Medical Quickie QX (K072153).

Intended Use
The Dignity 100 is a manually operated device with wheels that is intended for medical purposes to provide mobility to physically challenged persons. The Dignity 100 is intended for indoor and outdoor use on firm surfaces free of climbing obstacles.

Device Description
The Dignity 100 is a manually operated device with wheels that is intended for medical purposes to provide mobility to physically challenged persons. The Dignity 100 is intended for indoor and outdoor use on firm surfaces free of climbing obstacles.

The Dignity 100 functions like a standard mechanical wheelchair with the addition of a custom cushion. This 21 CFR Sec. 890.3920 wheelchair component is intended for medical purposes and sold as an integral part of the wheelchair, but will also be sold separately as a replacement part. The custom cushion is designed with a keyhole shaped drop down panel which is lever activated by the patient when he or she wishes to use the toilet.

The Dignity 100 is constructed from 7/8 inch outside diameter (OD) round, mechanical steel tubing. The chair is of welded construction. The sewn components are secured to the frame using screws and bolts. This device is a rigid wheelchair that incorporates a seating surface. The Dignity 100 has removable footrests.

Substantial Equivalence Comparison
The Dignity 100 is substantially equivalent to the Sunrise Medical/Quickie Design Model "Quickie QX Manual Folding Wheelchair" (K072153).

Performance Data
The Dignity 100 wheelchair passed all technical requirements identified in ANSI/RESNA parts 1, 3, 5, 7, 8 and 93.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 09 2008

Dignity Medical Devices, Inc.
%The Tamarack Group, Inc
Ms. Charmaine Sutton
16917 73rd Place North
Maple Grove, Minnesota 55311

Re: K082246
Trade/Device Name: Dignity 100
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair.
Regulatory Class: Class I
Product Code: IOR
Dated: July 31, 2008
Received: August 08, 2008

Dear Ms. Sutton:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082246

Dignity Medical Devices, Inc.
Dignity 100

510(k) Premarket Notification

510(k) Number (if known): _____

Device Name: Dignity 100

Indications for Use:

To provide mobility for the disabled.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office Of Device Evaluation (ODE)

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

510(k) Number K082246

(Posted November 13, 2003)