



Mr. Thomas E. Finch III  
Vice President  
Teftec Corporation  
12450 Network Boulevard  
San Antonio, Texas 78249

**FEB 08 2002**

Re: K013307

Trade/Device Name: Model Z105 Omega Trac® Powered Wheelchair  
Regulation Number: 890.3860  
Regulation Name: Powered wheelchair  
Regulatory Class: II  
Product Code: ITI  
Dated: December 20, 2001  
Received: December 26, 2001

Dear Mr. Finch:

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.

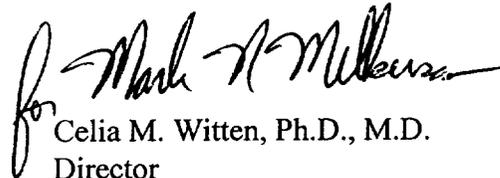
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Mr. Thomas E. Finch III

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

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

510 (k) NUMBER (IF KNOWN): K013307

DEVICE NAME: Model Z105 OmegaTrac® Powered Wheelchair

INDICATIONS FOR USE:

Indications for use for the Model Z105 OmegaTrac® Powered Wheelchair base:

OmegaTrac® design definitions and functional parameters are indicated for usage for anyone with limited mobility due to weak, amputated or non-functional extremities or improper, unsafe or non-existent gait patterns. Also, due to the specific driving control supplied by the transaxle, persons with spasticity or ataxic movements in their extremity's that are not candidates for other types of mobility without extensive modification may be appropriate for the OmegaTrac® with no modifications.

This usage would be indicated but not limited to the following types of injury's:

- |                                     |  |
|-------------------------------------|--|
| Spinal Cord Injury (SCI)            | Guillain-Barre Syndrome                    |
| Head Injury (CHI)                   | Quadriplegia                               |
| Muscular Dystrophy (MD)             | Paraplegia                                 |
| Cerebral Palsy (CP)                 | Triplegia                                  |
| Brown Sequard's Syndrome            | Hemiplegia                                 |
| Severe Arthritics (RA) (OA)         | Tetraplegia                                |
| Multiple Sclerosis                  | Proximal Extremity Weakness                |
| Huntington's Corea                  | Cerebral Vascular Accident (CVA or Stroke) |
| Traumatic Brain Injury (TBI)        | Quadriparesis                              |
| Amyotrophic Lateral Sclerosis (ALS) | Obesity                                    |
| Anoxic Encephalopathy               | Parkinson's                                |
| Anoxia                              |  |

This is not meant to be an all-inclusive list, anyone needing power assistance with their mobility may be an appropriate client for an OmegaTrac® powered wheelchair. This would usually be decided by clinical evaluation of the client's strength, sitting balance, mobility needs, size constraints and driving capability at their local rehab facility.

If you have any further questions, please feel free to contact us directly.

**(Please Do Not Write Below This Line-Continue On Another Page If Needed.)**

Concurrence of CDRH/Office of Device Evaluation (ODE)

*[Handwritten Signature]*  
for (Division Sign-Off)

Division of General, Restorative and Neurological Devices

Prescription Use \_\_\_\_\_ OR \_\_\_\_\_ Over-The-Counter-Use \_\_\_\_\_  
(Per 21 CFR 801.109) 510(k) Number K013307 (Optional Format 1 - 2 - 96)