DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Mr. Thomas E. Finch III
President
TEFTEC Corporation
6929 Old Spring Branch Road
Spring Branch, Texas 78070

Re: K993160
Trade Name: OmegaTrac® Powered Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 10, 1999
Received: October 26, 1999

Dear Mr. Finch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K993160

DEVICE NAME: ΩmegaTrac® Powered Wheelchair

INDICATIONS FOR USE:

Indications for use for the ΩmegaTrac® Powered Wheelchair base:

ΩmegaTrac® 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 ΩmegaTrac® with no modifications.

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

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

This is not meant to be an all-inclusive list, anyone needing power assistance with their mobility may be an appropriate client for an ΩmegaTrac® 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)

Prescription Use _____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Revised 11/13/1998

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993160