

SEP 3 1996

1K950025

DataTran Inc. ■▶□

Man/Machine System Innovators

December 26, 1994

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Bld.
Rockville, Maryland 20850

Re: 510(k) Self Propelled Robotic Wheel (SPRW),
Owner / Operator No. 9011753

Attention: Document Mail Clerk

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92." With this letter DataTran Inc., the developer of the Self Propelled Robotic Wheel (SPRW) requests that the Office of Device Evaluation (ODE) review the enclosed Premarket Notification 510(k) submission.

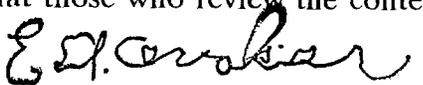
This 510k will show that the SPRW has a "predicate device" which was sold by SOLO PRODUCTS INC., on the interstate market, during the years 1975 to 1983. It began to be sold prior to May 28, 1976; and in accordance with the Federal Food, Drug and Cosmetic Act, 513(i)(1)(A),(1)(2), if ODE agrees, it is requested that they transmit to DataTran, a "Substantially Equivalent 510(k) letter."

DataTran has determined that the SPRW, when mounted on a wheelchair frame, converts manually operated wheelchairs to powered wheelchairs, and falls under class II as defined by 21 CFR 807. DataTran has "Taken action to assure performance", by having made arrangements with the University of Pittsburgh to verify our assertion that the SPRW device/system is in compliance with the ANSI/RESNA 1991 Wheelchair Standard.

The features described in the section of the Premarket Notification 510(k) entitled, **SAFETY AND EFFECTIVENESS OF THE SPRW**, are as follows: 1.) All the components for driving the wheels are rigidly supported in a central disc structure forming the wheel cavity; 2.) The cavity is fully enclosed by cosmetic covers; 3.) The components have been chosen for longevity to outlast two or more wheelchair frames; 4.) The resulting wheels can be quickly interchanged with the standard wheels of a manually operated wheelchair; 5.) A direct gear drive; 6.) The pancake motor with a state of the art rare earth neodymium-Iron-Boron magnet, makes this motor one of the most powerful for it's size; 7.) The SPRW is the first time that, a wheel used for transportation, has rotating within it: it's own power source, power conversion means (electrical to mechanical), power electronics photo-optic signal transmission at the hub between rotating and non-rotating components.

Notwithstanding that there is at least one "predicate device" that the SPRW is "substantially equivalent" to, the SPRW system includes innovations such as the infrared transmission link. These features are subject of a patent application which has been formally allowed for filing by the US Patent Office, to issue in mid 1995. This link is at least as safe and reliable as any signal transmission path used by the "predicate devices" for controlling speed and direction of the wheelchair. In no way do the innovations alter the "intended use" or the technologies used for the "predicate devices." The prime motivation for introducing the innovations is safety and effectiveness for the SPRW system.

Within the enclosed 510(k) there is information which is proprietary to DataTran Inc.,. It is requested that those who review the contents of the 510(k) **maintain this confidentiality.**


Emik A. Avakian, President
Contact person

12-26-94
Date