DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2001

Mr. Sylvain Dugas
President
AMYSYSTEMS
178 West Service Road
Champlain, New York 12919

Re: K011006
Trade Name: Amyseat Tilt/Recline Seating
Regulation Number: 890.3860
Regulatory Class: II
Product Code: ITI
Dated: April 18, 2001
Received: April 19, 2001

Dear Mr. Dugas:

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,

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

8.1.1. Statement of indications for use

510(K) number (if known): K011006
Device Name: AmySEAT TILT/RECLINE SEATING SYSTEM

Indications for use:

The AmySEAT TILT/RECLINE SEATING SYSTEM'S intended use and function is to provide a change of position without having to utilize the services of an attendant. Needs for position changes include:

1. **Pressure Relief**– From time to time, redistribution of pressure from one area of the body to another, can be done by tilting or reclining. By changing the user's orientation in space, pressures caused by gravity will shift.
2. **Positioning** – User's without adequate upper-body stability can be tilted to allow gravity to hold them in position.
3. **Comfort** - As with any person, ambulant or disabled, changes in position are necessary to maintain a state of comfort.

AmySystems makes no claims as to then therapeutic effectiveness of the products. Our only claims relate to the ability of the products to provide safe and reliable powered repositioning on the wheelchairs onto which they are installed. The AmySEAT TILT/RECLINE SEATING SYSTEM are to be factory installed or installed by a qualified dealer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K011006

Prescription Use_____ OR Over-The-Counter Use_____
(per 21 CFR 801.109)