DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Donald R. McIntyre, Ph.D.
Vice President and Chief Operating
Interlogics, Inc.
P.O. Box 1239
Hillsborough, North Carolina 27278

Re: K971079
Interlogics W-Tracker and Wristworks Software
Regulatory Class: I
Product Code: KQX
Dated: June 6, 1997
Received: June 9, 1997

JUL - 9 1997

Dear Dr. McIntyre:

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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K971079

Indications for Use

510(k) Number: K971079
Device Name: W-Tracker and WristWorks software
Indications for Use:

The W-Tracker is a bi-axial wrist-joint movement assessment device mounted on a forearm and hand. Specifically, it measures angular range of motion and velocity in two planes. The Clinical Analysis protocol requires the subject to perform a series of wrist movements, including wrist flexion/extension and ulnar/radial deviation, each to be performed by the subject at his/her preferred speed. The data obtained during the Clinical Analysis protocol is real-time data, and is immediately transferred from the W-Tracker to the computer via an A/D conversion device to a serial port.

The goals of the device when performing the Clinical Analysis protocol is to compile information related to tests devised by the AMA to measure impairment of wrist joints, and to compare performance profiles of normal and injured populations.

The W-Tracker does not initiate or control any movement during a test and it does not induce any forces on the subject. It is, therefore, a passive device. The only forces acting on the subject are the negligible inertial forces of the W-Tracker generated by the subject's wrist movements. The device is fail-safe in design to obviate safety concerns for the subject.

(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 Devices
510(k) Number K971079

Prescription Use X OR Over-The-Counter Use _____
(per 21 CFR 801.109)