K980363

APR 16 1998 **510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

CONTACT PERSON:

Ronald E. Tura

P.O. Box 1082

Alamo, CA 94507

DEVICE NAME:

Oro-Facial Myographic Measurement Instrument (OMMI™) Class II

DEVICE DESCRIPTION:

The Oro-Facial Myographic Measurement Instrument (OMMI™) is a myographic measurement method for direct strength measurement of the oro-facial muscles.

INDICATIONS FOR USE:

The Oro-Facial Myographic Measurement Instrument is intended as a diagnostic aid for the quantitative evaluation of oro-facial muscle strength.

PREDICATE DEVICE:

John Chatillon & Sons, Inc. Dynamometer (K964685).

TESTING in SUPPORT of SUBSTANTIAL EQUIVALENCE DETERMINATION:

The results of bench testing (Pressure Validation) and biocompatibility evaluation support the substantial equivalence claims of the OMMI™ for its intended use in the oro-facial cavity. Results of the test, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the OMMI's substantial equivalence to the predicate device.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

Substantial equivalence is based on the fact that the Oro-Facial Myographic Measurement Instrument has the same intended use, although different indications, and similar technological characteristics as the predicate device. In instances where the technological characteristics are different, it has been demonstrated that there are no new questions raised regarding safety or efficacy of the Oro-Facial Myographic Measurement Instrument. Therefore, it can be concluded that the Oro-Facial Myographic Measurement Instrument is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1998

Mr. Ronald E. Tura
President
OROFACIAL DYNAMICS
P.O. Box 1082
Alamo, California 94507

Re: K980363
Oro-Facial Myographic Measurement Instrument (OMMI™)
Regulatory Class: II
Product Code: LBB
Dated: January 23, 1998
Received: January 29, 1998

Dear Mr. Tura:

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 Stephen Rhodes

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

510(k) Number (if known): K980363

Device Name: ORO-Facial myographic measurement instrument (OMMI)

Indications For Use:

The Oro-Facial Myographic Measurement Instrument is intended as a diagnostic aid for the quantitative evaluation of oro-facial muscle strength. It is indicated for use in the oro-facial cavity.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980363

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)