JAN 1 1 2000

K992256

EXHIBIT 2

Intercontinental New Technologies, Inc.
1389 Bristol Lane
Buffalo Grove, IL 60089
Tel. 847-955-0311
Fax 847-955-0311
Contact: Aleksey Shlyakhta, President
June 30, 1999

510(k) Summary of Safety and Effectiveness

a) **Identification of the Device:**
Proprietary-Trade Name: Frolov's Respiration Training Device, FRTD-01
Classification Name: 73BWF
Common/Usual Name: Breathing training device

b) **Equivalent legally marketed devices This product is similar in design and function to the Mini-Ciser, K974848**

c) **Indications for Use (intended use) The device is for use as a Positive Expiratory Pressure (PEP) device and Inspiratory Muscle Trainer (IMT) in one device.**

d) **Description of the Device: The breathing trainer includes an inner chamber, an outer chamber, a breathing tube, and a perforated bottom cap to the inner chamber. Four teaspoons of water (20 ml.) are placed in the outer chamber and the patient breaths in and out of the breathing tube. The training effect is caused by the added pressure of the water. US Patent Number 5,755,640.**

e) **Safety and Effectiveness, comparison to predicate device. The results of bench and user testing indicates that the new device is as safe and effective as the predicate device.**

f) **Conclusion. After analyzing both bench and user testing data, it is the conclusion of Intercontinental New Technologies, Inc. that the Frolov's Respiration Training Device, FRTD-01 is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2000

Mr. Daniel Kamm
Intercontinental New Technologies, Inc.
c/o Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K992256
Frolov's Respiration Training Device, FRTD-01
Regulatory Class: II (two)
Product Code: 73 BWF
Dated: October 13, 1999
Received: October 14, 1999

Dear Mr. Kamm:

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 legally marketed predicate 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 requirements, 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Joanne A Witten

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K992256

Device Name: Frolov's Respiration Training Device, FRTD-01

Indications for Use: The device is for use as a Positive Expiratory Pressure (PEP) device and Inspiratory Muscle Trainer (IMT) in one device, for use by adults and children. The device is for single patient use, not for use on multiple patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992256