K012492
1 OF 3

NOV 0 2 2001

Summary

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

1. Company making the submission:

	Company	or	Correspondent (contract):
Name: Address: Telephone: Contact:	KaDa Research, Inc. 10701 Corporate Drive Ste. 100 Stafford, Texas 77477 281-437-9119 voice 281-240-7122 fax William C. Paske, Ph.D. President & CEO		Delphi Consulting Group 11874 South Evelyn Circle Houston, Texas 77071-3404 713-723-4080 voice 208-694-6953 fax J. Harvey Knauss Consultant

2. Device:

Proprietary Name:	KaDance Hand Sensor System
Common Name:	Force measurement device
Classification Name;	AC-powered dynamometer

3. Predicate Devices;

Digit-grip with LCD K981730

4. Classifications Names & Citations:

21 CFR 888.1240 AC-powered dynamometer, Class II, LLB, 87 Orthopedics.

5. Description:

The KaDance 2000 system is designed to aid in the identification of fine motor performance issues, (median nerve entrapment), which may be present in either or both hands of a human. The system is non-invasive. This is accomplished by measuring how the thumb (digit 1), index finger (digit 2) and little finger (digit 5) maintain a grip throughout several repetitive exercisers. These measurements are basically the applied forces exerted by the digits measured as a function of time. Measurements may be made as rapidly as once every 2 ms for all three digits

simultaneously.

K012492
2 OF 5

The system consists of 1) hand sensor, 2) a data control module and laptop computer, 3) KaDaLink™computer with KaDance 2000 software running. Data is displayed as force over time.

Operation of the system is menu driven from the laptop computer. When a subject test without errors has been completed, the data is transmitted to a central location via modem or other hi-speed data transmission means and hard copies are produced. Data is returned to test director by whatever means as directed. Interpretation of data and any diagnosis resides with the test director or other medical practitioner.

6. Indications for use:

- Any situation where the hand grip or pinch strength would be a valuable piece of data in the evaluation of a person who has sustained an injury or suffers a disease of his/her hand(s).
- To measure grip or pinch strength in an injured and uninjured hand.
- To conduct pre-employment screening for physically demanding job activities.
- To establish an industrial strength testing program in general, and to match the strength of workers to the strength demands of specific job duties in the workplace.

7. Contra-indications:

Should not be use on a subject with burns, open wound, rash or fracture. Use with caution when subject hands are sensitive to pain. Do not counter accepted clinical practice or institution guidelines.

8. Comparison:

The KaDance™ device has the same device characteristics as the predicate devices, except the predicate devices do not have the capability to transmit data to a distance location.

9. Test Data:

The KaDance device has been subjected to extensive safety, performance, and validations prior to release. Final testing for the systems includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies to applicable industry and safety standards.

10. Literature Review:

A review of literature pertaining to the safety and effectiveness has been conducted. Appropriate safeguards have been incorporated in the design of the KaDance™ device.

K012492

3 OF 3

11. Conclusions:

The conclusion drawn from these tests is that the KaDance device is equivalent in safety and efficacy to its predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 2 2001

KaDa Research, Inc.
c/o Mr. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071

Re: K012492
Trade/Device Name: KaDance 2000 Hand Sensor System
Regulation Number: 21 CFR 888.1240
Regulation Name: AC-powered dynamometer
Regulatory Class: Class II
Product Code: LBB
Dated: July 31, 2001
Received: August 3, 2001

Dear Mr. Paske:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

for Mark N Millar

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

510(k) Number K 012492

Device Name: KaDance 2000 Hand Sensor System

Indications for use:

- Any situation where the hand grip or pinch strength would be a valuable piece of data in the evaluation of a person who has sustained an injury or suffers a disease of his/her hand(s).
- To measure grip or pinch strength in an injured and uninjured hand.
- To conduct pre-employment screening for physically demanding job activities.
- To establish an industrial strength testing program in general, and to match the strength of workers to the strength demands of specific job duties in the workplace.

Prescription Device: NO

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)

for Mark N Milhersen

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

510(k) Number K012492

(Optional Format 1-2-96)