OCT 7 1998

K982425

F

PREMARKET NOTIFICATION 510(K) SUMMARY

1. **Submitters Name**: David L Mitchelson

2. **Address**: Charnwood Dynamics Limited
17 South Street, Barrow Upon Soar,
Leicestershire, LE12 8LY,
United Kingdom

3. **Telephone No**: +44 (0) 1509 620 388
Facsimile: +44 (0) 1509 416 791

4. **Date Prepared**: 24th June 1998

5. **Trade Name**: CODA mpx30 Motion Analysis System

6. **Common Name**: Motion Analysis System

7. **Classification Name**: System / Optical Position / Movement Recording

8. **Identification of Predicate Device(s):**

OrthoTrak II (K 890076)

9. **Device Description**:

CODA mpx30 is an optical/electronic system which measures and analyses the 3D position and movement of markers placed on the limbs of patients whose movement function is to be assessed.

Dimensions: 30mm wide x 114mm high x 250mm deep
Weight: 11 kg

10. **Intended use**:

The Coda mpx30 system has general application to measurement and recording of 3D position and movement, including human movement. It is appropriate for use in assessment of the 3D motion of the limbs and body of patients who have some impairment of movement functions of either a neurological or orthopaedic cause.

11. **Technological characteristics in comparison with predicate device**:

The Coda mpx30 system is substantially equivalent to the Ortho Trak system as a means of measuring the general three dimensional movement of patients, including such activities as walking. Both systems provide a non-intrusive optical method of measuring the movements using infra-red light. Both systems acquire the movement data into a host PC which then analyses and displays the data on graphs and printed reports.

The Coda system provides the advantages of LED markers which are automatically identified, whereas the Ortho Trak system uses reflective markers which have no intrinsic identity.

12. **Safety and Effectiveness Summary**:

The Coda system is designed and manufactured to meet the electrical safety requirements of EN 61010. There is no electrical connection to the patient of any kind. The system does not produce sources of localised heat so no thermal safety hazard arises. The system does not generate any ionising radiation.

The CODA mpx30 system has been tested for its effectiveness in measuring 3-D motion and producing graphical and mechanical data on gait and other movements as compared with the predicate device. The resolution and sampling rate at which the data were acquired by the CODA mpx30 system were significantly improved. Also the speed with which the analysed data became available was improved due to the automatic recognition of marker identity. All other aspects of the system performance were similar to the predicate device.

13. **510 (K) Number**: Not assigned at the time of submission.

14. **Conclusion**:

The CODA mpx30 system performs the same measurement functions using substantially similar technology as the predicate device.

The LED markers used provide for greater effectiveness in performance and the CODA mpx30 system meets all relevant safety standards. Consequently it 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

OCT 7 1998

Mr. Lee A. Barnes
President
Pinsco, Inc. dba B & L Engineering
3002 Dow Avenue, Suite 416
Tustin, California 92780

Re: K982425
Trade Name: CODA mpx30 Motion Analysis System
Regulatory Class: Unclassified
Product Code: LXJ
Dated: June 24, 1998
Received: July 13, 1998

Dear Mr. Barnes:

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

D

STATEMENT OF INDICATIONS FOR USE

The Coda mpx30 system has general application to measurement and recording of 3D position and movement, including human movement. It is appropriate for use in assessment of the 3D motion of the limbs and body of patients who have some impairment of movement functions of either a neurological or orthopaedic cause.

Over-the-Counter Use X

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982425