K073269

510(k) Summary

APR 18 2008

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter's Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726
1. (b)	***Manufacturer Address:***	HypnoCore, Ltd. 3 Hazoran Street, Sappir Industrial Park Netanya Israel, 42506
	Mfg. Phone:	972-9-8858075
	Contact Person:	Shuli Eyal, Ph.D.
	Date:	March 20, 2008
2.	***Device & Classification Name:***	Breathing Frequency Monitor (Class 2), Product Code MNR, 21 CFR 868.2375 – Tradename of device: HC1000P Sleep Diagnosis Software System.
3.	***Predicate Device:***	Compass F10 System (K041904) Noga Automated Sleep Study Scoring and Data Management System (K070326)
4.	***Description:***	HypnoCore's HC1000P is a sleep diagnosis software application. This software is used as an aid in the diagnosis of sleep and sleep related breathing disorders. The HC1000P is able to acomplish this by analyzing continuous ECG and pulse oxygen saturation data acquired from a sleeping patient. The interpretation of the results provided by the HC1000P software package is performed in conjunction with clinical information and examination of the patient obtained by a trained professional familiar with sleep medicine.
5.	***Intended Use:***	HC1000P software analysis's ECG and pulse oxygen saturation data acquired from a sleeping patient. It may be used as an aid in the diagnosis of sleep and sleep related breathing disorders.
6.	***Comparison of Technological Characteristics:***	With respect to technology, the HC1000P Sleep Diagnosis Software System is substantially equivalent in that the results it produces, are valid when compared against the gold standard and its predicate devices. This was statistically confirmed through a retrospective analysis against a clinical study.

1. INTRODUCTION

1.1. *WHAT IS HC1000P?*

HC1000P by HypnoCore is a novel propriety ECG based diagnostic system for sleep disorders.

1.2. *INTENDED USE*

HC1000P software analyzes ECG and pulse oxygen saturation data acquired from a sleeping patient. It may be used as an aid in the diagnosis of sleep and sleep related breathing disorders.

1.3. *DISCLAIMER*

This software is intended as a decision support system for persons who have received appropriate medical training, and should not be used as a sole basis for making clinical decisions pertaining to patient diagnosis, care, or management. Any deviation of the application of medical information from the program, other than the original design or intended use there of, is not advised and considered a misuse of the software product.
For additional guidance see published studies.

1.4. *DOCUMENT CONVENTIONS*

Pay particular attention at specific points in a procedure when one of the following messages appears:

CAUTION:

***Cautions** indicate instructions that if not followed may result in damage to the software or sub optimal results.*

NOTE:

***Notes** provide pertinent information to help obtain optimum performance from the software.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

HypnoCore, Limited
C/O Mr. George J. Hattub
Senior Staff Consultant
MedicSense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

APR 18 2008

Re: K073269
Trade/Device Name: HC1000P Sleep Diagnosis Software System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: April 3, 2008
Received: April 7, 2008

Dear Mr. Hattub:

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.

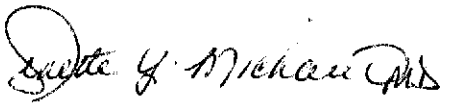
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073269

Device Name: HC1000P Sleep Diagnosis Software System

Indications For Use: HC1000P software analyzes ECG and pulse oxygen saturation data acquired from a sleeping patient. It may be used as an aid in the diagnosis of sleep and sleep related breathing disorders.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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