K072014

5 510(k) Summary

This summary statement complies with 21CFR, section 807.92(c).
Date summary prepared: 6 July 2007

This premarket notification has been submitted by Vitascore B.V. and covers the Vitascore polysomnography scoring software.

Submitter

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The Netherlands
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NOV 0 8 2007

Contact person

Wim Martens (Frank Aniba)
General Manager (QA Manager) Vitascore B.V.

Identification

The trade name is:	Vitascore
The common name for this type of device is:	Polysomnography scoring software
The classification name is:	MNR Ventilatory effort Recorder

The above as stated in 21 CFR, part 868.2375, has been classified as regulatory Class II.

Predicate device

Vitascore is substantially equivalent to the 'Compumedics Sleep Monitoring System', cleared under 510(k) number K955841.

Vitascore is a software program to

- score respiratory events
- score sleep stages and arousal
- indicate markers as for lights off/on
- produce customizable statistical reports.

Vitascore acts on

- long-term recordings that include all physiological signals that are required for clinical PolySomnoGraphy according to established standards

for subsequent

- diagnosis of sleep- and sleep-related disorders

Vitascore includes

- a workflow concept to handle the processing of sleep recordings

- optionally: automatic pre-scoring of respiratory events and sleep and arousal and EEG frequency analysis

This pre-analysis yields particular summary trend curves that facilitate the manual re-scoring.

Registered Polysomnographic Technicians and Physicians will use the program on pre-recorded PSG sleep recordings on stand-alone PC's or in a networked environment.

Intended use

The Vitascore software is a computer program, intended to be used as an aid for the diagnosis of sleep and respiratory disorders.

The Vitascore software is intended to be used for analysis (semi-automatic and manual re-scoring), display (similar to the use of a traditional paper based polygraph), redisplay (retrieve), summarize, to generate User defined reports, networking and managing of data received from devices that are typically used to evaluate sleep- and sleep related respiratory disorders.

Vitascore is to be used under supervision of a physician

Substantial Equivalence

The modified Vitascore system has the following similarities to those which previously received 510(k) concurrence:

- Has the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Incorporates similar materials, and
- Is manufactured and packaged using the same materials and processes.

Conclusion: Given the similarity between the modified Vitascore system vs. the'Compumedics Sleep Monitoring System' predicate device, cleared under 510(k) number K955841, we believe the device, as changed, does not raise any new issues of safety and effectiveness and is substantially equivalent to the predicate device previously cleared.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2007

Mr. Wim Martens
General Manager Quality Assurance Manager
Vitascore B.V.
Kromstraat 3
Gemert, Netherlands 5421 XZ

Re: K072014
Trade/Device Name: Vitascore
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: October 25, 2007
Received: October 29, 2007

Dear Mr. Martens:

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.

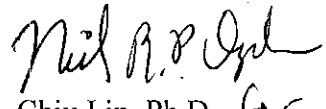
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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. for
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

Indication for Use

510(k) number (if known): K072014

Device Name: Vitascore

Indications For Use:

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Prescription Use _√_ AND/ OR Over-The-Counter Use _____
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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