biocomfort

K081499

510(k) Summary

JAN 16 2009

The assigned 510(k) number is K081499

Date Prepared	September 23, 2008
Submitter Information	Biocomfort Diagnostics GmbH & Co KG Bernhaeuser Strasse 17 73765 Neuhausen a d F Germany Registration Number 3006493236 Owner/Operator Number 10023755
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US Agent (Contact)	Mr Dieter Schill President Biocomfort Inc 23 Third Avenue Burlington, MA 01803 USA Phone +1 866 294 8267 E-mail schill@biocomfort com

Device Trade Name	Health Manager 2 0
Common Name	Transmitters and receivers, physiological signal, radiofrequency
Device Classification Name	Radiofrequency physiological signal transmitter and receiver
Product Code	DRG
Device Classification No	Part 870 2910
Regulatory Status	Class II

Predicate Devices	
Device Trade Name	Confidant 2 5
510(k) Number	K072698
Device Classification Name	Radiofrequency physiological signal transmitter and receiver
Product Code	DRG
Device Classification No	Part 870 2910
Regulatory Status	Class II

Device Description

The Biocomfort Health Manager is a software for local home PC or Laptop in a non clinical environment HM can manage up to 8 users With the HM the Biocomfort devices can be bound with the USB-Dongle from Biocomfort After the devices are bound and programmed with HM, the user can measure with the devices

Intended Use

The Biocomfort Health Manager is a software for local home PC or Laptop in a non clinical environment to collect historical data from defined peripheral devices The software will receive, store and display measurements from home use diagnostic medical devices such blood pressure meter and a body composition analyser The data will not be used for medical diagnosis It is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgement

SE Discussion

		Substantial Equivalent Device	**Predicate Devices**	
		Biocomfort Health Manager	**Confidant 2 5**	**Discussion of differences**
[01]	**Indication for use**	The Biocomfort Health Manager is a software for local home PC or Laptop in a non clinical environment to collect historical data from defined peripheral devices The software will receive, store and display measurements from home use diagnostic medical devices such blood pressure meter and a body composition analyser The data will not be used for medical diagnosis It is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgement	Confidant 2 5 is intended for personal use by out-of-hospital patients as a means to retrospectively collect and record physiologic measurements from home monitoring devices (including blood glucose meters, blood pressure cuffs and weight scales) The data is transmitted to a database server where customized messages are generated by the system and returned to the patient The returned messages contain objective observations and motivational information intended to help the patient better understand and manage their health Confidant 2 5 is an accessory device that collects data from a range of supported home-monitoring devices The	Equivalence except No transmission of data to data base server with the Health Manager software No use of cell phone technology with the Health Manager Software

		Substantial Equivalent Device	Predicate Devices	
		Biocomfort Health Manager	**Confidant 2 5**	**Discussion of differences**
			data is collected from the supported devices and sent to a central database server, using standard wireless technologies Upon receipt of newly submitted patient data, the Confidant Server software will generate and send one or more feedback messages directly to the patient's cell-phone The feedback messages are selected by the system based on the patient's currently submitted and recent historic data Confidant 2 5 does not provide diagnosis of any disease or medical condition Confidant 2 5 is not intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional Confidant 2 5 is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data This device is not intended as a substitute for direct medical supervision or emergency intervention Confidant 2 5 is intended	

		Substantial Equivalent Device	Predicate Devices	
		Biocomfort Health Manager	**Confidant 2 5**	**Discussion of differences**
			for over-the-counter use	
[02]	**Target population**	Lay users	Lay users	Equivalent
[03]	**Connected Medical Devices**	Blood Pressure Meter Body Composition Analyzer	Blood Pressure Meter Blood Glucose Meter Weight Scale Meter	Equivalent except for Body Composition Analyzer instead of weight scale and the Health Manager does not read data from a blood glucose meter
[04]	**User interaction**	Additional requests regarding user behaviour	Additional requests regarding user behaviour	Equivalent
[05]	**Presentation of results**	In table and graphical form Printout of reports	In text and graphical form	Equivalent except with printout function
[06]	**Health Management Guidance**	Graphical depiction of health status via target attainment graph and provision of hints	Graphical depiction of average measuring results and motivational information	Equivalent
[07]	**Operation environment**	Windows based PC Software	Cell Phone based Software	PC based software instead of cell phone based software
[08]	**Transmission of data**	Data transmission only between peripheral measuring devices and the Health Manager Software	Data transmission to peripheral measuring devices and central database server	Equivalence except No communication to central data server
[09]	**Connectivity**	Radiofrequency	Radiofrequency	Equivalent

Discussion of the Substantial Equivalence Decision.
The comparison shows that both devices are substantial equivalent The only differences are that the predicate device transmits the data to a database server which is not the intention of the Biocomfort Health Manager and that the Health Manager does not use cell phone technology or cell phone based software

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2009

Biocomfort Inc
c/o Mr Dieter Schill
President
23 Third Ave
Burlington, MA 01803

Re K081499
Health Manager 2 0
Regulation Number 21 CFR 870 2910
Regulation Name Radiofrequency physiological signal transmitter and receiver
Regulatory Class II
Product Code DRG
Dated November 18, 2008
Received November 21, 2008

Dear Mr Schill

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 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 (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Bram D Zuckerman, M D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K081499

Device Name Health Manager 2 0

The Biocomfort Health Manager is a software for local home PC or Laptop in a non clinical environment to collect historical data from defined peripheral devices The software will receive, store and display measurements from home use diagnostic medical devices such blood pressure meter and a body composition analyser The data will not be used for medical diagnosis It is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgement

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 11/4/01

Division of Cardiovascular Devices

510(k) Number K081499