510(k) Summary
(As Required by 21 C.F.R. §807.92)

Submitted by:

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Date of summary: December 19, 2003

Device name: VST$^3$

Common name: Vital Signs Recorder and Transmitter

Classification names:

| Regulation No. and Class | Description |
|---|---|
| 870.2920, II | Telephone ECG Transmitter and Receiver (Telephone) |
| 870.2800, II | Medical Magnetic Tape Recorder Ambulatory ECG (without analysis) |
| 870.2300, II | User Physiological Monitor (without arrhythmia detection or alarms) |

Predicate Devices

The VST$^3$ is substantially equivalent to the following cleared predicate devices:

K012223

Device Description

The VST$^3$ is an ambulatory ECG monitor. It is a wearable device capable of monitoring two channels of electrocardiogram. The device monitors each of the input channels and stores the information for later transmission via its cellular modem to a trained critical care specialist located at a remote clinical monitoring center. It provides real-time, continuous, interventional monitoring over extended periods of time. Additionally, upon receipt of appropriate commands, the device is capable of opening a cellular voice channel and/or transmitting its location information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2004

Biowatch Medical, Inc.
c/o Mr. Ned Devine
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K040942
Trade Name: VST$^3$ Vital Signs Recorder and Transmitter
Regulation Number: 21 CFR 870.2920
Regulation Name: Electrocardiograph Telephone Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: August 27, 2004
Received: August 30, 2004

Dear Mr. Devine:

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 (301) 594-4646. 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 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,

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): K040942

Device Name: Biowatch Medical VST$^3$

Indications for Use:

The Biowatch Medical VST$^3$ is indicated for use to monitor adults with abnormal heart rhythms and other symptoms of cardiac disease, such as:

- Arrhythmia or dysrhythmia
- Skipped beats or pauses
- Rapid, slow, or irregular heart rate
- Lightheadedness or faintness
- Palpitations

The VST$^3$ records and transmits ECG data to a remote central receiving station for interpretation by certified critical care specialists and/or a licensed over-read physician to identify cardiac rhythm disorders. The device is not intended to sound any alarms

For Over-the-Counter Use.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices



510(k) Number K040942