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## ATTACHMENT 9

### 510(k) Summary For The InterCure Ltd. RESPeRATE

#### Submitter's Name, Address, Telephone Number, and Contact Person

InterCure Ltd.  
9 Hamelacha st. Kislev building  
Northern Industrial area, Lod, 71520 Israel

Contact: Dr. Benjamin Gavish  
Chief Scientist, InterCure Ltd.  
Phone: 972-8-9212126  
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**Date Prepared:** January 2002

#### **Name of the Device**

RESPeRATE

#### **Common or Usual Name**

Biofeedback Device

#### **Predicate Device**

Respi-Low Model RL-108 (K000495) manufactured by InterCure Ltd.;

#### **Intended Use**

The RESPeRATE is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure, together with other pharmacological and/or non-pharmacological interventions.

### **Summary of the Basis for the Finding of Substantial Equivalence**

The RESPeRATE is substantially equivalent to InterCure's previously cleared Respi-Low biofeedback device (K000495) for use in stress reduction and adjunctive treatment to reduce blood pressure. The device shares the same general intended use in relaxation and/or stress reduction and the same indications for use except for OTC use. Moreover, the principles of operation are identical to the predicate device and there are only minor differences in technological characteristics. Clinical testing in the OTC setting has shown that the RESPeRATE device can be properly used without the direction of a physician. This difference in the specific indications for use of the RESPeRATE (for OTC use) compared to the predicate (for prescription use), however, does not raise new questions of safety or efficacy and does not alter its therapeutic effect. Moreover, the clinical study demonstrated a safe, clinically significant, reduction in high blood pressure with use of the RESPeRATE over a period of 8 weeks without the guidance of a physician. Therefore, the devices are substantially equivalent.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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InterCure LTD.  
c/o Jonathan S. Kahan  
Hogan and Hartson, L.L.P.  
555 13<sup>th</sup> Street, N.W.  
Washington, D.C. 20004-1109

Re: K020399  
Trade Name: RESPeRATE  
Regulation Number: 882.5050  
Regulation Name: Biofeedback device  
Regulatory Class: II  
Product Code: HCC  
Dated: May 9, 2002  
Received: May 9, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket 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) 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.

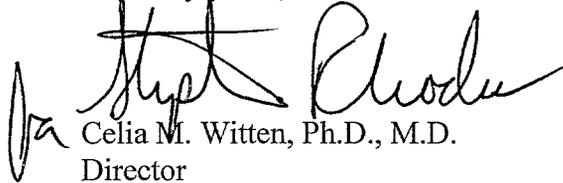
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K020399

Device Name: InterCure Ltd. RESPeRATE

Indications for Use:

The RESPeRATE is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure, together with other pharmacological and/or non-pharmacological interventions.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use X

(Per 21 C.F.R. 801.109)  
(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K020399