APR 2 7 2001

Oxford Instruments Medical Ltd
Manor Way, Old Woking, Surrey GU22 9JU, United Kingdom
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510(k) Summary

1. General Information

Trade Name of Device:	Sonicaid® System 8002
Common/Usual Name:	Fetal heart rate analysis software
Classification Name:	System, monitoring, perinatal
Submitters Name & Address:	Oxford Instruments Medical Ltd Manor Way Old Woking Surrey GU22 9JU United Kingdom Tel +44 (0)1483 770331 Fax +44 (0)1483 727193
Contact Name:	E. J. Smith Consultant
Manufacturer:	Oxford Instruments Medical Ltd Manor Way Old Woking Surrey GU22 9JU United Kingdom

2. Device Description

The Sonicaid® System 8002 is a software accessory for the computerized analysis of antepartum cardiotocograms (CTGs) in pregnancies from 32 weeks gestation onwards. It informs the clinician whether a CTG meets a number of criteria that are indicative of a normal CTG.

3 Indications for Use

The Sonicaid® System 8002 is for use in pregnancies from 32 weeks gestation and greater. It can be used on women who are experiencing Braxton-Hicks contractions but is not suitable for use in established labour as the fetus is then exposed to additional factors such as labour contractions, pharmacological agents, epidural anaesthesia, and the possibility of fetal infection secondary to ruptured membranes. Typical indications for use include the following:

– previous questionable fetal heart rate recordings or poor obstetric history
– abnormal umbilical blood flow velocity waveforms
– suspected fetal anomalies
– suspicion of maternal intoxication or assault
– intrauterine growth retardation
– antepartum haemorrhage
– uterine pain
– reduced fetal movements
– hypertension or pre-eclampsia
– reduced amniotic fluid volume

The Sonicaid® System 8002 is used as an adjunct to and is not intended to replace or substitute for assessment of amniotic fluid amount, Doppler evaluations, and/or biophysical profile.

4. Substantial Equivalence

The Sonicaid® System 8002 is substantially equivalent to the Sonicaid® Team fetal monitor K912639.

5. Performance Studies

The Sonicaid® System 8002 informs the clinician whether a CTG meets a number of criteria that are indicative of a normal CTG. Software verification studies were performed in-house to establish the correctness of these criteria, and clinical validation studies have been performed and documented supporting the use of these criteria in the determination of a normal CTG.

6. Conclusion

Based upon the indications for use and performance studies the Sonicaid® System 8002 has been shown to be suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2001

Oxford Instruments Medical Ltd
c/o Ms. Yolanda Smith
Smith Associates FDA Consultants
P.O. Box 4341
CROFTON MD 21114

Re: K992607
Sonicaid® System 8002 (software accessory)
Dated: March 29, 2001
Received: April 3, 2001
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Ms. Smith:

We have reviewed your Section 510(k) 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 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K992607

Device Name: Sonicaid® System 8002

Classification Panel: 85HGM

Indications for Use:

The Sonicaid System 8002 is for use in pregnancies from 32 weeks gestation onwards. It can be used on women who are experiencing Braxton-Hicks contractions but is not suitable for use in established labour as the fetus is then exposed to additional factors such as labour contractions, pharmacological agents, epidural anaesthesia, and the possibility of fetal infection secondary to ruptured membranes. Typical indications for use include the following:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or Over the Counter Use** _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992607