AUG 25 2005 K050234

APPENDIX A: SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary for the Remote Care by e.Care Solutions.

SUBMITTER'S NAME:	e.Care Solutions
ADDRESS:	1345 Wilmington Island Road Savannah, GA 31410
CONTACT PERSON:	Constance G. Bundy
TELEPHONE NUMBER:	763-574-1976
FAX NUMBER:	763-571-2437
DATE OF SUBMISSION:	31 January 2005

1. **Identification of device**
   Proprietary Name: Remote Care
   Common Name: Perinatal Monitoring System Accessory
   Classification Status: Class II per regulations 884.2740, Perinatal Monitoring System and Accessories
   Product Codes: HGM

2. **Equivalent devices**
   e.Care Solutions believes the Remote Care is substantially equivalent to Analogic FETALGARD Lite™ by Analogic Corporation, 510(k) # K002503.

3. **Description of the Device**
   Remote Care is an internet database application and repository for the storage and archival of patient information with their physiological data that relates to the Remote Care OB customers' prenatal experience. "Remote Care" receives data from the Analogic FETALGARD Lite™ and makes the data available to the medical professional through the World Wide Web.

4. **Intended use**
   "Remote Care" is a patient management web based application device for use with the Analogic FETALGARD Lite™ to record and graphically display maternal abdominal contractions and the fetal heart rate by means of a display in the format of a graphic or PDF strip file. The data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy (Non-Stress Test). This device is for trained medical personnel located in hospitals, clinics, doctor's offices and in the patient's home.

5. Indications for Use

Remote Care is intended to be used only with the Analogic FETALGARD Lite™ to assist in the transmission and graphical display of maternal abdominal contractions and fetal heart rate. Remote Care receives the strip data from the monitoring system via a modem or the CareStation video phone. This strip data is then transmitted to the Remote Care web site for viewing by the health care provider.

Remote Care does **not** provide real-time capabilities or alerts. The device is intended for use to communicate strip data which can be used to aid in assessing the well being of the fetus in the final trimester of pregnancy. Healthcare professionals must apply clinical judgment and experience to assess the data transmitted. The device is not intended as a replacement for professional medical care. It should not be used for patients requiring emergency intervention.

6. Technological characteristics, comparison to predicate device.

"Remote Care" is an accessory to the Analogic FETALGARD Lite™ by Analogic Corporation and is similar in many respects. Remote Care receives data from the Analogic device and graphically displays the data in similar format to the Analogic device. The primary difference is that "Remote Care" has features for increased security and patient database solution, scalable application and database, and World Wide Web accessibility. Remote Care offers an enterprise solution with a security role management process supporting an organization, department and person.

Comparative Table

	Feature	Remote Care e.Care Solutions	Analogic FETALGARD Lite™ Analogic Corporation
1.	Fetal Monitor	Analogic FETALGARD Lite™ monitor	Analogic FETALGARD Lite™ monitor
2.	Data Receiver	Analogic FETALGARD Lite™ data receiver	Analogic FETALGARD Lite™ data receiver
3.	FHR/URM Rendering	Analogic FETALGARD Lite™ Viewer - Modified For Multi-user access & the Web	Analogic FETALGARD Lite™ Viewer - Client Machine Only & Single User
4.	Input	Analogic FETALGARD Lite™ data receiver and key board entry from the "Remote Care" web user interface	Analogic FETALGARD Lite™ data receiver and key board entry from Analogic FETALGARD Lite™ Viewer client interface
5.	Output	Screen and Adobe PDF file – see Substantial Equivalence "Remote Care" Output submitted with this document	Screen and Paper – see Substantial Equivalence FETALGARD Lite™ Output submitted with this document
6.	Printing	YES	YES
7.	Patient Database	YES – Extensive – Microsoft SQL Server	YES – Limited – Microsoft Access
8.	Reporting	Yes	NO
9.	Multi-User	YES	YES - Limited
10.	WEB Enabled	YES	NO

7. Discussion of functional testing.

Tests has been conducted and successfully completed, including functional compliance to specifications and performance comparison to the predicate device.

8. Conclusion

Based on performance testing and a comparison to the predicate device, it is the conclusion of e.Care Solutions that the Remote Care is substantially equivalent to devices already on the marked (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2005

e.Care Solutions, Inc.
% Ms. Constance G. Bundy
Consultant
C. G. Bundy Associates, Inc.
6740 Riverview Terrace
FRIDLEY MN 55432

Re: K050234
Trade/Device Name: Remote Care
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring systems and accessories
Regulatory Class: II
Product Code: HGM
Dated: July 14, 2005
Received: July 19, 2005

Dear Ms. Bundy:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K050234

Device Name: Remote Care

Indications for Use:

Remote Care is intended to be used only with the Analogic Fetalgard Lite to assist in the transmission and graphical display of maternal abdominal contractions and fetal heart rate. Remote Care receives the strip data from the monitoring system via a modem or the CareStation video phone. This strip data is then transmitted to the Remote Care web site for viewing by the health care provider.

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

K050234