Section 5

510(k) Summary

MAR 1 1 2011

CIV-ob (plus) Obstetrical Data Management and Monitoring Software Application

510(k) Number K_____

Applicant's Name: CIVNET Communication Ltd.
Hatamar St. 58,
Moshav Hemed, Israel 50295
Tel: 972-3-7568824
Fax: 972-3-9607842
E-mail: Nathy@civnet.co.il

Contact Person: Nathan Ben-nathan
Tel: 972-504331000
E-mail: Nathy@civnet.co.il

Date: June 10, 2010

Trade Name: CIV-ob™ (plus) Obstetrical Data Management and Monitoring Software Application

Common Name: Perinatal monitoring system

Classification:
HGM, 21 CFR § 884.2740, for Perinatal Monitoring System and accessories, Class II

Identification of Legally Marketed Predicate Devices:

CIVNET believes that the CIV-ob™ (plus) Obstetrical Data Management and Monitoring Software Application used to monitor Obstetrical fetal/maternal monitors and their related EMR (Electronic Medical Record) data is substantially equivalent to:

- CIVNET CIV-ob Obstetrical Software Application, cleared under K051175.

- Barnev Inc. BIRTHTRACK (A.K.A. CLM) Computerized Labor Monitoring System cleared under K082704.

without raising new safety and/or effectiveness issues.

A discussion of substantial equivalence is provided in **Section 12** of this submission.

Device Description:

The CIVNET CIV-ob™ (plus) Obstetrical Data Management and Monitoring software application is for remote display, archiving and data management of fetal/maternal bedside monitor and/or Birth Tracking monitors. The CIVNET CIV-ob™ (plus) is intended for use as a clinical data management and monitoring system for multiple bedsides with the added ability to connect multiple monitors to a single bed side. The CIVNET CIV-ob™ (plus) is indicated for maternal/fetal vital signs data management and is suitable for the hospital and clinical environment.

The CIVNET CIV-ob™ (plus) Data Management and Monitoring software application is intended for automatic fetal/maternal monitoring and patient data management. The application does this by:

a) Providing Obstetrical Data Management and remote display of information and graphs from Obstetrical monitors.
b) Displaying real time fetal heart rate and TOCO data HS and CD data received from the patient bed-side in a one-to-one representation as it is displayed on the fetal/maternal monitor.
c) Providing the means to display multiple beds simultaneously.
d) Providing automatic Archiving of the data.
e) Providing Administrative Control to ensure that the system performs without technical failure.
f) Providing easy interfacing with any IT patient record system for data acquisition, viewing and storage of electronic patient record.
g) Providing visual notification of fetal/maternal monitor alerts such as out of limit heart rate or poor signal quality.
h) Providing the ability to record as part of the patient record, fluid input and output information that is defined by the user.
i) Providing the user the ability to enter comments and specific data.
j) Providing the ability to archive files to a secondary or tertiary storage medium (i.e. optical disk).
k) Providing the ability to print (locally or remotely) patient records and CIV-ob™ (plus) data base definition (e.g. item names).
l) Providing the ability to connect multiple monitors to a single bed side.

The role of the CIV-ob™ (plus) software remains the same as the CIV-ob™ in that the CIV-ob™ (plus) system is designed to archive electronic data provided by the fetal/maternal monitor, and to display real-time graphical data received from the monitor via the hospital network.

The CIV-OB™ (plus) system is comprised of five modules:

1. Main Server (with an option of multiple servers per site)
2. Mid Server for every Birth Tracking monitor
3. Monitoring Station
4. Central monitor module
5. Site Sniffer control and revision module

The CIVNET CIV-ob™ (plus) is a modification of the CIVNET CIV-ob™. It contains the same functions, with the following additions:

- The development environment tool used is Microsoft ".Net" developing environment.
- Display of Cervix dilation birth tracking parameter
- Display Fetal head decent birth tracking parameter
- Display of all birth tracking alert messages present on the birth tracking monitor is part of the remote monitoring.

CIVNET CIV-OB™ (plus) is intended to be marketed in three configurations.

- Configuration 1 - CIV-OB™ (plus) for Data Management and Monitoring of both obstetrics and birth tracking
- Configuration 2 - CIV-OB™ (plus) for Data Management and Monitoring of obstetrics only
- Configuration 3 - CIV-OB™ (plus) for Data Management and Monitoring of fetal birth tacking only

Intended Use

The CIVNET CIV-ob™ (plus) is a clinical data managing software application and is indicated for antepartum and intrapartum monitoring of pregnant women in a healthcare setting

The CIVNET CIV-ob™ (plus) is indented to manage perinatal monitoring data acquired from bedside monitors or manual inputs for viewing at the central nursing station. The system also produces an electronic medical record.

The CIVNET CIV-ob™ (plus) has display fields for the following obstetric data:

- Monitoring site details
- Patient demographics
- Provider notes
- FHR

- Uterine Activity (via tocodynamometry IUP)
- Head Decent
- Cervix Dilation

Summary of Technological Characteristics of device compared to predicate devices

The CIV-ob™ (plus) has been updated from the predicate version (K051175). There have been no changes to the intended use or fundamental scientific technology.

The software of the CIV-ob™ (plus) has been updated to introduce several new features. The changes to the software include the addition of the birth tracking parameters as part of the fetal monitoring application.

Summary of Non-Clinical testing for the device and conclusions

The CIV-ob™ (plus) has been thoroughly tested through verification of its specifications and validation of its software. Verification of compliance with the following standards has also been made to support the safety of the device in its intended environment.

- IEC 60601-1-4 Programmable Electrical Medical Systems
- IEC 62304 Software Life Cycle for Medical Devices
- Compliance with 21 CFR Part 11 Rule on electronic records and signatures.

Summary of clinical testing for the device and conclusions

The modifications made to the CIV-ob™ (plus) did not require clinical testing.

Conclusion:

The summary above shows that there are no new questions or safety and effectiveness issues for the CIV-ob™ (plus) when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 1 1 2011

Mr. Nathan Ben-nathan
Chairman
CIVNET Communication Ltd.
Hatamar St. 58
Moshav Hemed
ISRAEL 50295

Re: K103172
Trade/Device Name: CIV-ob™ (plus)
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: March 8, 2011
Received: March 11, 2011

Dear Mr. Ben-nathan:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

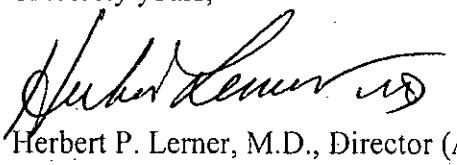
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Section 4

Indications for Use Statement

INDICATIONS FOR USE

510(k) Number (if known): K103172

Device Name: **CIV-ob™ (plus)**

Indications for Use: The CIVNET CIV-ob™ (plus) is a clinical data managing software application and is indicated for antepartum and intrapartum monitoring of pregnant women in a healthcare setting

The CIVNET CIV-ob™ (plus) is indented to manage perinatal monitoring data acquired from bedside monitors or manual inputs for viewing at the central nursing station. The system also produces an electronic medical record.

The CIVNET CIV-ob™ (plus) has display fields for the following obstetric data:

- Monitoring site details
- Patient demographics
- Provider notes
- FHR
- Uterine Activity (via tocodynamometry IUP)
- Head Decemt
- Cervix Dilation

Prescription Use ___X___ (Per 21 CFR 801.109 subpart D) OR Over the Counter Use_____ (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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103172