DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2007

Barnev Ltd.
% Ms. Ahava Stein
A. Stein Regulatory Affairs Consulting, Ltd.
242 Sunset Avenue
ENGLEWOOD NJ 07631

Re: K060028
Computerized Labor Monitoring System
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 884.2800
Classification: Class II
Product Code: NPB

Dear Ms. Stein:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Computerized Labor Monitoring System. This system is intended for monitoring the active phase of labor in women with term pregnancies, vertex presentation, and ruptured membranes. It is intended to be placed when cervical dilation is between 3 cm and 7 cm. The device continuously measures cervical dilation and fetal head station with ultrasound transducers attached to the maternal abdomen and cervix and to the fetal scalp. These measurements are displayed numerically and graphically as a function of time to show the progress of labor. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Computerized Labor Monitoring System and substantially equivalent devices of this generic type into class II under the generic name, Labor Progression Monitoring System. This order also identifies the special controls applicable to this device, entitled, "Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems."

FDA identifies this generic type of device as:

21 CFR 884.2800 Computerized Labor Monitoring System

A computerized labor monitoring system is a system intended to continuously measure cervical dilation and fetal head descent and provide a display that indicates the progress of labor. The computerized labor monitoring system includes a monitor and ultrasound transducers. Ultrasound transducers are placed on the maternal abdomen and cervix and on the fetal scalp to provide the matrix of measurements used to produce the display.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On October 18, 2006, FDA filed your petition requesting classification of the Computerized Labor Monitoring System into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on October 5, 2006 automatically classifying the Computerized Labor Monitoring System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or one which was subsequently reclassified into class I or class II. In order to classify the Computerized Labor Monitoring System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device type for its intended use.

After review of the information submitted in the petition, FDA has determined that the Computerized Labor Monitoring System is intended for monitoring the active phase of labor in women with term pregnancies, vertex presentation, and ruptured membranes. It is intended to be placed when cervical dilation is between 3 cm and 7 cm. The device continuously measures cervical dilation and fetal head station with ultrasound transducers attached to the maternal abdomen and cervix and to the fetal scalp. These measurements are displayed numerically and graphically as a function of time to show the progress of labor. The device can be classified in class II with the establishment of special controls for class II. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

The potential risks to health associated with the device are: patient injury, electrical hazards, acoustical (ultrasound) tissue damage, electromagnetic interference and electrostatic discharge hazards, mismanagement of the patient, adverse tissue reaction, and infection. The special controls guidance document aids in mitigating the risk by establishing performance characteristics, guiding

nonclinical analysis and testing, identifying when clinical data are needed, and developing appropriate labeling.

In addition to the general controls of the act, the Computerized Labor Monitoring System is subject to the following special controls: the guidance document entitled, "Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems." Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device type is not exempt from the premarket notification requirements. Thus, persons who intend to market this type device must submit to FDA a premarket notification submission containing information on the computerized labor monitoring system they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Glenn Bell, Ph.D., at (240) 276-4100.

Sincerely yours,

Miriam C Provost

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