

K955559

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**Corometrics Fetal Movement Detection Kit
510(k) Summary**

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Prepared: 30 November 1995

[807.92(a)1] Contact Information

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[807.92(a)2] Device Name and Classification

The proprietary name of the modified device to be introduced into interstate commerce is the Corometrics Fetal Movement Detection Kit

Common names include: FMD Kit

As indicated in this premarket notification submission, the Corometrics Fetal Movement Detection Kit is a class II device. To date no formal classification name has been issued for similar devices. Applicable device classification names include: § 884.2960 Obstetric ultrasonic transducer and accessories, and §884.2740, perinatal monitoring system.

[807.92(a)3] Identification of Legally Marketed Equivalent Devices (Predicate Systems)

Hewlett-Packard Fetal Movement Profile (FMP) Option in the M1350A Fetal Monitor
(k900480: clearance date - July 2, 1990)

[807.92(a)4 & 807.92(a)5] Device Description & Intended Use

The FMD Kit is a modular hardware/software kit that can be installed in a Corometrics Fetal Monitor. The FMD Kit provides the ability to automatically detect fetal movement via pulse Doppler ultrasound and to display the duration of such events on the fetal monitor's recorder strip chart as horizontal bars along the time scale (time axis) of the heart rate scale.

The Corometrics Fetal Movement Detection (FMD) Kit is intended to detect gross fetal body movements and fetal body movements with associated limb movement. Corometrics defines "gross fetal body movement" as the extension, flexion, or rolling over of the fetal trunk about the longitudinal axis of the body and associated limb movements." Movement of the extremities alone may not be detected. Fetal eye movements will not be detected.

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[807.92(a)6] Predicate Device Comparison of Technological Characteristics

Feature	(Predicate) Hewlett-Packard Fetal Movement Profile (FMP)	Corometrics Fetal Movement Detection (FMD)
Detection method	Pulse Doppler Ultrasound Technique	Same
Detection of gross body movements via ultrasound transducer	Yes	Same
Annotated by bar/dot	Yes	Same
Annotated by spike waveform	No	Same
Optional function	Yes	Same

[807.92(b)1, 807.92(b)2 & 807.92(b)3] Performance Standards per the Food, Drug and Cosmetic Act

To date, no performance standards relating to devices of this type have been promulgated by the Food and Drug Administration.

[807.92(d)] Additional Information

Bench testing and clinical evaluations were performed and verified the equivalent performance of the Corometrics Fetal Movement Detection Kit with the Hewlett-Packard Fetal Movement Profile (FMP).