9.0 510(k) SUMMARY: Corometrics 120 Series

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[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 120 Series Maternal/Fetal Monitor. Common names include: 120 Series, 120 MFM.

As with the predicate Model 118, the 120 Series is a Class II device.

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

Predicate System	Manufacturer	k Number
Model 118 Maternal/ Fetal Monitor	Corometrics Medical Systems, Inc. 61 Barnes Park Road North Wallingford, CT 06492	k934959, clearance date: 10/15/94
Model 556 Critical Care Monitor		k911310, clearance date: 6/10/91

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

The 120 Series is intended for monitoring fetal and maternal vital signs: fetal heart rate; and maternal uterine activity, heart/pulse rate, blood pressure, and %$Sp0_2$. The device is intended for use in a hospital/clinical environment.

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

Monitoring Mode	120 Series	Model 118	Model 556
FHR/UA Monitoring	Yes	Yes	Not Applicable
Maternal Heart/Pulse Rate, NBP, $Sp0_2$ Monitoring	Yes	Yes	
MECG Waveform	Yes	No	Yes

[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

The 120 Series has been extensively tested to meet its requirements and design.