K954351

P -- [510(k)] Summary of Safety and Effectiveness

The Series 50XM (M1350B) is a combination of two subsystems which represent either the functionality of the Fetal Monitor Series 50IX (M1350A) or it will represent the functionality of parts of the Patient Monitors HP 78352C or M1020A (SpO2) and M1008B (NBP).
The Series 50 XM (M1350B) therefore combines all of the basic fetal monitoring requirements and maternal NBP, SpO2 and ECG in one monitor which is the same intended use as for the predicate device Corometrics Model 118.

The intended use of the fetal monitoring is the same as for the predicate device Series 50IX (M1350A).
It allows non- invasive or invasive monitoring of an ambulant patient during both antepartum testing and labor and delivery in that the monitoring of the FHR via ultrasound or direct ECG, and uterine activity via an external Toco transducer or an internal IUP transducer is possible, additionally it allow maternal heart rate recording via the MECG transducer.

The intended use of the maternal parameters NBP and SpO2 is the same as for the predicate devices HP78352C, M1020A and M1008B
It allows the non-invasive measurement of the Noninvasive Bloodpressure ans the Oxygen Saturation ,generate alarms, and generate recording on maternal patients.

The fetal parameters are displayed in the same way as that currently used on the Series 50IX (M1350A).

The additional maternal parameters are displayed on a separate LCD display situated between the fetal parameters and the recorder.

The Series 50XM (M1350B) slightly modifies existing software modules of the Series 50IX (M1350A) Fetal Monitor (which was originally cleared under K900480) and adds a new Software Modules for the maternal parameters, which were original transported from the predicate devices of HP.

The HP Series 50XM (M1350B) was fully validated (including regression testing).

The comparison of intended use and technological characteristics of this device to other legally marketed devices taken together with the validation results and other information in this submission indicate that this device is substantially equivalent to legally marketed predicate devices in safety, effectiveness, and intended use.