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AEQUITRON MEDICAL

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510(k) SUMMARY

This summary of 510(k) Premarket Notification safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) and 21 CFR 807.92.

Device Name:

The proprietary name of the device to be introduced into interstate commerce by Aequitron Medical, Inc. is the Ami Infant Central Apnea/Heart Rate Monitor.

Classification:

The Ami Infant Central Apnea/Heart Rate Monitor is classified as a "Breathing Frequency Monitor" (21 CFR 868.2375).

The device classification is Class II.

Predicate Device(s):

The Ami Infant Central Apnea/Heart Rate Monitor is substantially equivalent to the Aequitron Medical, Inc. Model 9550 Cardiorespiratory Monitor.

Device Description:

The Ami Infant Central Apnea/Heart Rate Monitor is capable of monitoring an infant's respiratory and heart rates. The device utilizes respiration detection technology for respiratory effort detection and also detects ECG rate through the same two electrodes. The device also incorporates auxiliary inputs for recording stand-alone oximeter output parameters and/or other devices' signal outputs within specified parameters. The device operates off either battery of AC power.

Indications for Use:

Use of the Ami Infant Central Apnea/Heart Rate Monitor is indicated for the continuous monitoring of an infant's heart rate and respiration rate in a home, hospital or portable environment. Continuous monitoring is indicated for infants whose physical condition may result or has resulted in an instability in heart rate or respiration which may become detrimental to the infant. Conditions which may require monitoring include (not all inclusive):

- Prematurity
- Respiratory dysfunction
- Neurologic dysfunction
- Maternal drug abuse
- Cardiovascular dysfunction

Description of Laboratory and Clinical Testing:

The Ami Infant Central Apnea/Heart Rate Monitor was subjected to detailed laboratory testing designed to fully exercise and evaluate device functionality, performance, safety and effectiveness under conditions such as the presence of electrostatic discharge (ESD), electric and magnetic field interference (EMI), mechanical vibration and shock, high and low temperature and humidity conditions.

Performance validation protocols and checklists were derived directly from the device specification to develop the test plan including all monitoring parameters. This laboratory testing utilized physiologic test simulators, test meters and other sophisticated electronic and mechanical measurement equipment which was maintained under strict calibration control.

The user interface was also tested during this phase. The Ami Infant Central Apnea/Heart Rate Monitor was found to meet all of the validation requirements verifying performance to the design specification.

Clinical evaluations were also conducted. The design of these studies assessed the performance and functionality of the Ami Infant Central Apnea/Heart Rate Monitor as compared to the predicate device, Aequitron Model 9550 and other reference monitors.

The results of these studies further demonstrated the proper functionality, safety and effectiveness and substantial equivalence to the predicate device.

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(Division Sign-Off)
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