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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is _____.

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Device Trade Name:
Sarns 8000 Cardioplegia Monitor

Device Classification Names:
"Blood Pressure Alarm" (21 CFR 870.1100), and
"Blood Pressure Computer" (21 CFR 870.1110), and
Monitoring Accessory to a "Roller-type cardiopulmonary bypass blood pump" (21 CFR 870.4370).

Predicate Devices:
The new *Sarns 8000 Cardioplegia Monitor* is substantially equivalent to the existing *Sarns 8000 Cardioplegia Monitor* (K915183) and the *Sarns 9000 Cardioplegia Control* (K871131).

Device Description:
The *Sarns 8000 Cardioplegia Monitor* is only compatible with the *Sarns 8000 Modular Perfusion System*. The *Sarns 8000 Cardioplegia Monitor* can display two pressures and three temperatures from attached probes. The pressure has alert and alarm levels which are set by the operator. The *Sarns 8000 Cardioplegia Monitor* also has a timer for use in tracking the time during and between doses of cardioplegia. With the new added features, it also displays the volume of cardioplegia delivered to the patient. The *Sarns 8000 Cardioplegia Monitor* communicates with the *Sarns 8000 Roller Pump* for obtaining volume information and to stop the roller pump (designated for cardioplegia delivery) during a pressure alarm condition if set by the operator to do so. The *Sarns 8000 Cardioplegia Monitor* also communicates with the *Sarns 8000 Data Communications Module* for purposes of data acquisition.

Indications For Use:
The *Sarns 8000 Cardioplegia Monitor* is indicated to measure extracorporeal line pressure and signal when the pressure exceeds the operator-set limit, either providing an alert or triggering an alarm which stops the cardioplegia pump only. The monitor also measures temperatures of the patient or extracorporeal circuit, counts the time during and between cardioplegia doses, and tracks the volume of cardioplegia delivered.

Technological Characteristics:
Compared to the existing *Sarns 8000 Cardioplegia Monitor*, the software has undergone modifications to read and display volume information from the *Sarns 8000 Roller Pump*. The *Sarns 9000 Cardioplegia Control*, part of the *Sarns 9000 Perfusion System*, is also used as a predicate device since it has the same features which are being added to the *Sarns 8000 Cardioplegia Monitor*. The modified *Sarns 8000 Cardioplegia Monitor* has no new technological characteristics compared to the predicate devices.

Nonclinical Performance:
The performance of the *Sarns 8000 Cardioplegia Monitor* and its interface with the *Sarns 8000 Modular Perfusion System* was exhaustively tested. All new and existing software functions as defined in the Software Requirements Specification were completely validated.

Clinical Performance:
Clinical testing was not performed on the device.

Conclusions from Nonclinical Tests:
The *Sarns 8000 Cardioplegia Monitor* performs as intended according to its performance specification. The *Sarns 8000 Cardioplegia Monitor* is substantially equivalent to the predicate devices.