

OCT 11 1996

510(k) Summary**Flowtron®Excel AC550**

The AC550 Flowtron®Excel pump, coupled with the Flowtron DVT compression garments, is an external pneumatic compression system used to prevent deep vein thrombosis (DVT) in patients deemed to be at risk by their physicians. External pneumatic compression has been in use for almost twenty years, and the HNE Healthcare predicate device, Flowtron®DVT, received premarket clearance in 1988.

The AC550 Flowtron Excel pump is the next generation of the Flowtron DVT AC500 pump. Each pump has been designed to be used with the currently marketed Flowtron DVT calf and calf/thigh length compressible garments for the prevention of deep vein thrombosis (DVT). There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

The functional components of the pump (compressor, timing motor, valve) are the same. The predicate device, AC500, has an audible and visible (LED light) fault monitoring system that is comprised of logic electronics with a pressure switch input. The new device, AC550, also has an audible and visible (LED light and display) fault monitoring system, however, the input is from a pressure transducer that is microprocessor controlled. In both pumps, the alarm mechanism does not control the function of the pump, but provides a feedback of pump performance. Additionally, the new device will provide an indication of actual pump output pressures, which the predicate device does not do.

There are no performance standards established for this category of medical device (Class II - Compressible Limb Sleeves). Voluntary standards met include UL listing and compliance with the European Medical Directive for electromagnetic compatibility.

The Flowtron®Excel raises no new safety or effectiveness concerns.