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Appendix F

510(k) Summary

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STÖCKERT S3 PERFUSION SYSTEM CARDIOPLEGIA CONTROL MODULE

1. **Date Prepared:** June 14, 1996
2. **Submitter:** Stöckert Instrumente, GmbH
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4. **Device Name:** Stöckert S3 Perfusion System
Cardioplegia Control Module
5. **Device Classification:** Cardiopulmonary bypass consoles and their accessories have been classified as Class II devices in 21 CFR 870.4370 (Product Code: 74 DWB).
6. **Device Description and Comparison to Predicate Products:**

The Stöckert S3 Cardioplegia Control Module is an accessory module to the Stöckert S3 (cardiopulmonary bypass) Perfusion System, and is intended to control and monitor the use of cardioplegia solutions during the bypass procedure. The predicate and predecessor device to the S3 Cardioplegia Control Module is the Stöckert CAPS Cardioplegia Control unit. Similar devices have been used for many years for this same intended purpose. The newly modified Cardioplegia Control Module from Stöckert (the S3 Cardioplegia Control Module) is a simple upgrade of the technological aspects of the device, e.g., the software controls have been updated and the control and display panels have been updated for user convenience in operating the system.

Information supplied in this premarket notification to support a determination of Substantial Equivalence for this device included descriptive information about the design, materials, and intended use of the device, as well as extensive testing

results characterizing device performance, including electrical testing, functional testing, and software verification and validation testing. The Stöckert S3 Perfusion System console and modular components (including the Cardioplegia Control Module) conform with the applicable requirements of IEC 601, IEC 62a, and UL 544. The device holds the CE mark in the European Union.