

PREMARKET 510(k) NOTIFICATION
SUMMARY/CONCLUSION

K970755

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Conclusion

The submitted device meets the requirements of the Proposed Rule from 21 CFR Parts 895 and 897 regarding Protected Design Leadwires. Further, samples of the submitted device passed all applicable sections of the voluntary standard ANSI/AAMI EC53-1995. Also, samples of the submitted device passed additional testing, not a part of any standard. Based on the test results outlined in the *Specifications Section* of this Premarket 510(k) Notification, it is concluded that the submitted device raises no new concerns of safety or effectiveness, and should be considered *Substantially Equivalent* to the predicate devices listed in this submission.