510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
TRIAGE-QUICK REVIEW DECISION SUMMARY

510(k) Number: k190773

This 510(k) was reviewed under OIR's Triage-Quick Review Program. This program represents an internal workload management tool intended to reduce internal FDA review resources for 510(k) applications that are of good quality upon receipt by FDA.

The information in the 510(k) is complete and supports a substantial equivalence (SE) determination. Please refer to the applicant's 510(k) summary for a summary of the information that supports this SE determination.