510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION

TRIAGE-QUICK REVIEW DECISION MEMORANDUM

510(k) Number: K241428

This 510(k) was reviewed under the OHT7/OHT8 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.