

**K100523 ADULT CEREBRAL-SOMATIC OXIMETRY SENSOR,
PEDIATRIC CEREBRAL-SOMATIC OXIMETRY SENSOR MODEL
HHS-SAFB-SM, HHS-SPFB-USA**May 4, 2010
69 days to decisionK100523 · Product code: **NMD** · Cardiovascular
Source: <https://www.510kdatabase.net/k100523/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation, Reprocessed (NMD)
Date received	Feb 24, 2010
Decision date	May 4, 2010
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hygia Health Services, Inc.
Location	Birmingham, AL, US
Contact	LAKE TRECHSEL
510(k) history	14 submissions · 14 cleared · 2002-2010

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