

K081233 T-STAT 303 ISCHEMIA MONITORING SYSTEMJul 28, 2008
88 days to decisionK081233 · Product code: **MUD** · CardiovascularSource: <https://www.510kdatabase.net/k081233/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	May 1, 2008
Decision date	Jul 28, 2008
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spectros Corporation
Location	Portola Valley, CA, US
Contact	BILL CURNAN
510(k) history	3 submissions · 3 cleared · 2004-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081233/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026