

K052119 TESLAGUARD, MODEL EFT G04Jan 3, 2006
152 days to decisionK052119 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k052119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Aug 4, 2005
Decision date	Jan 3, 2006
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mammendorfer Institute For Physics & Medicine GmbH
Location	Golden, CO, US
Contact	ROBERT N CLARK
510(k) history	3 submissions · 3 cleared · 2003-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052119/> 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 May 25, 2026