

K101533 EX-TEM, FIB-TEM, AND AP-TEM FOR ROTEM DELTA THROMBOELASTOMETRY SYSTEMAug 10, 2011
433 days to decisionK101533 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k101533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jun 3, 2010
Decision date	Aug 10, 2011
Days to decision	433 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tem Innovations GmbH
Location	Munich, Bavaria/Upper Bavaria, DE
Contact	VOLKER-JOACHIM FRIEMERT
510(k) history	2 submissions · 2 cleared · 2011-2022

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