

K201440 ROTEM sigma Thromboelastometry SystemJul 8, 2022
767 days to decisionK201440 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k201440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jun 1, 2020
Decision date	Jul 8, 2022
Days to decision	767 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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