FDA 510(k) Premarket Notification

K242294 DiaSys Procalcitonin FS

CLEARED

May 9, 2025
280 days to decision

K242294 · Product code: **PTF** · Microbiology
Source: https://www.510kdatabase.net/k242294/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay To Measure Pct To Aid In The Risk Assessment Of Critically Ill Patients On Their First Day Of Icu Admission (PTF)
Date received	Aug 2, 2024
Decision date	May 9, 2025
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	DiaSys TruCal Procalcitonin Calibrator Set; DiaSys TruLab Procalcitonin Bi-Level Controls

APPLICANT

Company	**Diasys Diagnostic Systems GmbH**
Location	Holzheim, DE
Contact	Jan Gorka
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Imagenix, Inc.**
Contact	Stephen Gorski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov