FDA 510(k) Premarket Notification

K203035 Eonis SCID-SMA kit

CLEARED

Nov 9, 2022
765 days to decision

K203035 · Product code: **PJI** · Medical Genetics
Source: https://www.510kdatabase.net/k203035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Severe Combined Immunodeficiency Disorder (scid) Newborn Screening Test System (PJI)
Date received	Oct 5, 2020
Decision date	Nov 9, 2022
Days to decision	765 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Perkinelmer, Inc.**
Location	Indianapolis, IN, US
Contact	Eva Nalian
Website	http://www.perkinelmer.com
510(k) history	17 submissions · 15 cleared · 2009-2022

PerkinElmer, Inc. is a global provider of laboratory instruments, reagents, and analytical solutions. The company operates with a manufacturing facility in Indianapolis, US, and specializes in chemistry devices for clinical diagnostics and research applications. PerkinElmer received FDA 510(k) clearances from total submissions between 2009 and 2022. The company's cleared devices focus primarily on neonatal screening and mass spectrometry chemistry kits, along with diagnostic instrumentation. This regulatory record reflects the company's established presence in clinical la...