FDA 510(k) Premarket Notification

CLEARED

K200788 Assure Titanium Blood Glucose Monitoring System

May 23, 2022
788 days to decision

K200788 · Product code: **PZI** · Chemistry
Source: https://www.510kdatabase.net/k200788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Prescription Use Blood Glucose Meter For Near-patient Testing (PZI)
Date received	Mar 26, 2020
Decision date	May 23, 2022
Days to decision	788 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arkray, Inc.**
Location	Beverly, MA, US
Contact	Yosiharu Uehata
510(k) history	18 submissions · 18 cleared · 2002-2024

REGULATORY CONSULTANT

Consulting firm	**Arkray Factory USA, Inc.**
Contact	Dhwani Thakkar

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