FDA 510(k) Premarket Notification

K231974 PATHFAST®hs-cTnI-II

CLEARED

Mar 20, 2024
261 days to decision

K231974 · Product code: **MMI** · Chemistry
Source: https://www.510kdatabase.net/k231974/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jul 3, 2023
Decision date	Mar 20, 2024
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Phc Corporation**
Location	Tokyo, JP
Contact	Misato Igarashi
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Polymedco, Inc.**
Contact	Helen Landicho

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