FDA 510(k) Premarket Notification

K232670 HiCardi+ H100

CLEARED

Sep 20, 2024
385 days to decision

K232670 · Product code: **DSH** · Cardiovascular
Source: https://www.510kdatabase.net/k232670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 1, 2023
Decision date	Sep 20, 2024
Days to decision	385 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**MEZOO Co., Ltd.**
Location	Wonju-Si, KR
Contact	Junghwan Park
510(k) history	1 submissions · 1 cleared · 2024-2024