FDA 510(k) Premarket Notification

K771199 SURGIPULSE HEART RATE MONITOR

CLEARED

Jul 25, 1977
20 days to decision

K771199 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k771199/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jul 5, 1977
Decision date	Jul 25, 1977
Days to decision	20 days
Third-party review	No

APPLICANT

Company	**Stryker Corp.**
Location	Mchenry, IL, US
510(k) history	124 submissions · 121 cleared · 1976-2023

Stryker Corp. is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, implants, and patient safety technologies used globally across multiple medical specialties. Stryker has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company maintains active regulatory engagement, with its latest clearance in 2023. Its product portfolio spans orthopedic devices, neurosurgical implants, surgical instruments, and endoscopy systems, reflecting a broad pr...