CLEARED

Nov 15, 2024
197 days to decision

K241224 Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Medline ReNewal Reprocessed Biosense Webster Webster CS Catheter with EZ Steer Technology and Auto ID Technology (BD710DF282CT, BD710DF282RTS, BD710FJ282RTS, BD710FJ282CT)

K241224 · Product code: **NLH** · Cardiovascular
Source: https://www.510kdatabase.net/k241224/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Recording, Electrode, Reprocessed (NLH)
Date received	May 2, 2024
Decision date	Nov 15, 2024
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Surgical Instrument Service and Savings Inc.(Dba Medline Ren**
Location	Redmond, OR, US
Contact	Stephanie Boyle Mays
510(k) history	6 submissions · 6 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	**Surgical Instrument Service and Savings, Inc.**
Contact	Stephanie Boyle Mays

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