CLEARED

K994331 REVEAL PLUS INSERTABLE LOOP RECORDER SYSTEM, MODEL 9526 IMPLANTED RECORDER AND MODEL 6191 PATIENT ACTIVATOR

Jan 21, 2000
29 days to decision

K994331 · Product code: **MXC** · Cardiovascular
Source: https://www.510kdatabase.net/k994331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Dec 23, 1999
Decision date	Jan 21, 2000
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	NORA K HADDING
510(k) history	475 submissions · 453 cleared · 1977-2023