CLEARED

K013484 TELSTAR MAGNETIC NAVIGATION SYSTEMS [MNS}, TELSTAR BI-PLANE DIGITAL IMAGING SYSTEM, NIOBE ELECTROPHYSIOLOGY MAPPING CATH

May 2, 2002
195 days to decision

K013484 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k013484/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Oct 19, 2001
Decision date	May 2, 2002
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stereotaxis, Inc.**
Location	St. Louis, MO, US
Contact	PETER A TAKES
Website	https://www.stereotaxis.com
510(k) history	28 submissions · 28 cleared · 2002-2026

Stereotaxis, Inc. is a pioneer and global leader in innovative surgical robotics for minimally invasive endovascular intervention. The company develops robotic systems, instruments, and information solutions for the interventional laboratory. Stereotaxis operates with a manufacturing facility in St. Louis, Missouri. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. Cardiovascular devices represent 89% of the company's regulatory portfolio. Stereotaxis has maintained continuous FDA 510(k) activity since its first c...