FDA 510(k) Premarket Notification

K241895 Cannulated PsiFGuard

CLEARED

Sep 26, 2024
90 days to decision

K241895 · Product code: **SCY** · Orthopedic
Source: https://www.510kdatabase.net/k241895/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Guidewire Placement Device (SCY)
Date received	Jun 28, 2024
Decision date	Sep 26, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spineguard**
Location	Vincennes, FR
Contact	Stephane Bette
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John Smith

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