FDA 510(k) Premarket Notification

K203816 DeGen Navigated Instrumentation

CLEARED

Apr 2, 2021
94 days to decision

K203816 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k203816/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Dec 29, 2020
Decision date	Apr 2, 2021
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Degen Medical**
Location	Florence, SC, US
Contact	Craig Black
510(k) history	16 submissions · 16 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	**Secure BioMed Evaluations**
Contact	Linda Braddon

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