FDA 510(k) Premarket Notification

K192653 Perseus

CLEARED

Sep 9, 2020
351 days to decision

K192653 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k192653/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Sep 24, 2019
Decision date	Sep 9, 2020
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthokey Italia S.R.L.**
Location	Carrara, IT
Contact	Cristiano Paggetti
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Isemed S.R.L.**
Contact	Guido Bonapace

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