FDA 510(k) Premarket Notification

K202151 Smart SPACE Shoulder System

CLEARED

Feb 3, 2021
184 days to decision

K202151 · Product code: **QHE** · Orthopedic
Source: https://www.510kdatabase.net/k202151/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Arthroplasty Implantation System (QHE)
Date received	Aug 3, 2020
Decision date	Feb 3, 2021
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Techmah Medical, LLC**
Location	Knoxville, TN, US
Contact	Mohamed R. Mahfouz
510(k) history	3 submissions · 3 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Mary Vater

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