FDA 510(k) Premarket Notification

K203566 Tablet Application

CLEARED

May 13, 2021
157 days to decision

K203566 · Product code: **ODA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Central Control Unit (ODA)
Date received	Dec 7, 2020
Decision date	May 13, 2021
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew**
Location	Memphis, TN, US
Contact	Sean Reynolds
Website	http://www.smith-nephew.com/
510(k) history	17 submissions · 17 cleared · 2015-2025

Smith & Nephew is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in Memphis, US, and serves approximately 100 countries worldwide. The company has received FDA 510(k) clearances from total submissions since 2015. Orthopedic devices represent the dominant category, including pelvic and acetabular systems, patella plates, suture anchors, cable systems, external fixators, arthroscopes, and limb lengthening systems. The latest clearance was granted in 2025, confirming a...