FDA 510(k) Premarket Notification

K192876 INTELLIO Tablet Application

CLEARED

Feb 27, 2020
142 days to decision

K192876 · Product code: **ODA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k192876/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Central Control Unit (ODA)
Date received	Oct 8, 2019
Decision date	Feb 27, 2020
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew**
Location	Memphis, TN, US
Contact	Janice Haselton
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...