FDA 510(k) Premarket Notification

K222971 ULTRABUTTON QUAD Adjustable Fixation Device

CLEARED

Feb 17, 2023
143 days to decision

K222971 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k222971/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 27, 2022
Decision date	Feb 17, 2023
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ULTRABUTTON BB Adjustable Fixation Device; ULTRABUTTON TIB SMALL Adjustable Fixation Device; ULTRABUTTON TIB MEDIUM Adjustable Fixation Device; ULTRABUTTON TIB LARGE Adjustable Fixation Device

APPLICANT

Company	**Smith & Nephew, Inc.**
Location	Mchenry, IL, US
Contact	Dongeun LoPresti
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...