

K232005 HEALICOIL PK Suture Anchor with Needles, ULTRATAPE (Blue)

Aug 4, 2023
29 days to decision

K232005 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k232005/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jul 6, 2023
Decision date	Aug 4, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HEALICOIL PK Suture Anchor with Needles, ULTRATAPE (Blue Cobraid)

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	Camille Fleischer
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...