

K251627 BIORAPTOR 2.3 PK Suture Anchor w/ ULTRABRAID (#2) Suture (cobraid blue)Jun 25, 2025
28 days to decisionK251627 · Product code: MBI · Orthopedic
Source: <https://www.510kdatabase.net/k251627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 28, 2025
Decision date	Jun 25, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BIORAPTOR 2.3 PK Suture Anchor w/ ULTRABRAID (#2) Suture (cobraid black); BIORAPTOR 2.3 PK Suture Anchor w/ ULTRABRAID (#2) Suture (white); BIORAPTOR CURVED 2.3 PK Suture Anchor w/ ONE 38 ULTRABRAID (#2) Suture (cobraid black); BIORAPTOR CURVED 2.3 PK Suture Anchor w/ ONE 38 ULTRABRAID (#2) Suture (cobraid blue)

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	Crystal Treadway
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...