CLEARED

Oct 6, 2015
249 days to decision

K150209 Healix BR Anchor, Healix PEEK Anchor, Healix Transtend, Gryphon T and P BR Anchor, Gryphon PEEK Anchor, VersaLok Anchor, Bioknotless BR Anchor, Lupine BR Anchor, PanaLok Anchor,PanaLok Anchor with Orthocord, PanaLok RC QuickAnchor Plus

K150209 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k150209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Jan 30, 2015
Decision date	Oct 6, 2015
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary
Other names	PanaLok RC QuickAnchor Plus Dual Suture, PanaLok RC QuickAnchor Plus w/Orthocord; PanaLok RC QuickAnchor Plus Dual Suture w/Orthocord, PanaLok Loop Anchor, Lupine Loop Anchor, PanaLok RC Lop Anchor, BioKnotless Anchor, BioKnotless RC Anchor, RC Loop Anc

APPLICANT

Company	**Depuy Mitek, A Johnson and Johnson Company**
Location	Raynham, MA, US
Contact	YAYOI FUJIMAKI
510(k) history	3 submissions · 3 cleared · 2014-2015