

K223114 Suture Anchors - HTA Headless Titanium Anchor and Zip AnchorsAug 2, 2023
303 days to decisionK223114 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k223114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Oct 3, 2022
Decision date	Aug 2, 2023
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gm Dos Reis Industria E Comerico Ltda.
Location	Campinas, BR
Contact	Iara Guimaraes
510(k) history	3 submissions · 3 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Pr Servicos Regulatorios Administrativos Ltda
Contact	Homero Santiago Antunes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223114/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026