FDA 510(k) Premarket Notification

K211650 The Radian MIS Bunion System

CLEARED

Nov 24, 2021
180 days to decision

K211650 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k211650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 28, 2021
Decision date	Nov 24, 2021
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nvision Biomedical Technologies, Inc.**
Location	San Antonio, TX, US
Contact	Diana Langham
510(k) history	24 submissions · 24 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**Nvision Biomedical Technologies**
Contact	Analaura Villarreal-Berain

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov