

K210016 Integra DigiFuse Cannulated Intramedullary Fusion System,Integra Total Foot System,Integra CAPTURE Screw System & Integra Ti6 Internal Fixation System,Subtalar MBA System,MetaSurg Subtalar Implant,NewDeal BOLD Screw,NewDeal HALLU Lock Plate System,NewDeal HALLU Plates,QWIX Positioning Screw,SPIN Snap-Off Screw,NewDeal TIBIAXYS SystemJul 27, 2021
204 days to decisionK210016 · Product code: HRS · Orthopedic
Source: <https://www.510kdatabase.net/k210016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 4, 2021
Decision date	Jul 27, 2021
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Integra LifeSciences Corporation
Location	Planisboro, NJ, US
Contact	Blesson Abraham
510(k) history	65 submissions · 65 cleared · 2004-2025

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