FDA 510(k) Premarket Notification

K101030 MODIFICATION TO HBS HEADLESS BONE SCREW

CLEARED

Jun 3, 2010
51 days to decision

K101030 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k101030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 13, 2010
Decision date	Jun 3, 2010
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biopro, Inc.**
Location	Port Huron, MI, US
Contact	DAVID MRAK
510(k) history	41 submissions · 35 cleared · 1987-2017