FDA 510(k) Premarket Notification

K081608 PROXIMAL HUMERUS SCAFFOLD FIXATION SYSTEM (PHSFS)

CLEARED

Dec 19, 2008
193 days to decision

K081608 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k081608/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 9, 2008
Decision date	Dec 19, 2008
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Toby Orthopaedics, LLC**
Location	Miami, FL, US
Contact	AL WEISENBORN
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k081608/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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