FDA 510(k) Premarket Notification

K082399 PECTUS STRUT

CLEARED

Nov 5, 2009
442 days to decision

K082399 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k082399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 20, 2008
Decision date	Nov 5, 2009
Days to decision	442 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Koros USA, Inc.**
Location	Moorepark, CA, US
Contact	TIBOR KOROS
510(k) history	4 submissions · 4 cleared · 2007-2013