FDA 510(k) Premarket Notification

K080992 AESCULAP IMPLANT SYSTEMS HIGH TIBIAL OSTEOTOMY PLATING SYSTEM

CLEARED

Sep 4, 2008
150 days to decision

K080992 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k080992/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 7, 2008
Decision date	Sep 4, 2008
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap Implant Systems, Inc.**
Location	Center Valley, PA, US
Contact	Lisa Boyle
510(k) history	22 submissions · 22 cleared · 2007-2016