FDA 510(k) Premarket Notification

CLEARED

K063584 STERLING IF SCREW EYELET, MODEL CID3936 AND STERLING CROSS-PIN EYELET, MODEL CID3937

May 9, 2007
159 days to decision

K063584 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k063584/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Dec 1, 2006
Decision date	May 9, 2007
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Regeneration Technologies, Inc.**
Location	Alachua, FL, US
Contact	Lisa Simpson
510(k) history	11 submissions · 11 cleared · 2005-2008