

K080184 DISTAL HUMERAL PLATES WITH ANGULAR STABILITYMar 26, 2008
61 days to decisionK080184 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k080184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 25, 2008
Decision date	Mar 26, 2008
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	I.T.S. Implantat-Technologie-Systeme GmbH
Location	Prior Lake, MN, US
Contact	AL LIPPINOCOTT
510(k) history	13 submissions · 13 cleared · 2004-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080184/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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