

K040947 DURASUL BIPOLARAug 27, 2004
137 days to decisionK040947 · Product code: **KWY** · Orthopedic
Source: <https://www.510kdatabase.net/k040947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Apr 12, 2004
Decision date	Aug 27, 2004
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Centerpulse Orthopedics, Inc.
Location	Austin, TX, US
Contact	AUDREY SWEARINGEN
510(k) history	10 submissions · 10 cleared · 2003-2004

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