

K062856 TF ROTARY NICKEL TITANIUM FILEDec 13, 2006
79 days to decisionK062856 · Product code: **EKS** · Dental
Source: <https://www.510kdatabase.net/k062856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	File, Pulp Canal, Endodontic (EKS)
Date received	Sep 25, 2006
Decision date	Dec 13, 2006
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ormco Corp.
Location	Mchenry, IL, US
Contact	COLLEEN BOSWELL
510(k) history	40 submissions · 39 cleared · 1978-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 5, 2026