

**K894781 OPTIFLEX**Sep 15, 1989  
49 days to decisionK894781 · Product code: **EJF** · DentalSource: <https://www.510kdatabase.net/k894781/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Metal, Orthodontic (EJF)
Date received	Jul 28, 1989
Decision date	Sep 15, 1989
Days to decision	49 days
Third-party review	No

**APPLICANT**

---

Company	<b>Ormco Corp.</b>
Location	Mchenry, IL, US
Contact	FRANCES ZEE
510(k) history	40 submissions · 39 cleared · 1978-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894781/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 5, 2026