

**K171409 OT EQUATOR**Apr 9, 2018  
329 days to decisionK171409 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k171409/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 15, 2017
Decision date	Apr 9, 2018
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Rhein 83 Srl</b>
Location	Hoboken, NJ, US
Contact	Claudia Nardi
510(k) history	4 submissions · 4 cleared · 2004-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171409/> 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 May 30, 2026