

# K160158 NobelProcera HT ML FCZ Implant Bridge and Framework

Jul 25, 2016  
180 days to decisionK160158 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k160158/>

## SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jan 27, 2016
Decision date	Jul 25, 2016
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

---

Company	<b>Nobel Biocare AB</b>
Location	Goteborg, SE
Contact	Charlemagne Chua
Website	<a href="https://www.nobelbiocare.com">https://www.nobelbiocare.com</a>
510(k) history	92 submissions · 92 cleared · 2002-2026

Nobel Biocare AB is a medical device manufacturer based in Goteborg, Sweden. The company specializes in implant systems and related technologies for oral and maxillofacial applications. Nobel Biocare AB has received FDA 510(k) clearances from total submissions since 2002. The company's regulatory portfolio is dominated by Dental devices, which account for approximately 86% of submissions. Recent clearances include implant systems, abutments, and digital imaging software, with the latest FDA 510(k) clearance in 2026, demonstrating continued regulatory activity. The company...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k160158/> 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 2, 2026