

**K211396 Neoss Individual Prosthetics**May 17, 2022  
377 days to decisionK211396 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k211396/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 5, 2021
Decision date	May 17, 2022
Days to decision	377 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Neoss, Ltd.</b>
Location	Washington, DC, US
Contact	Stellan Sundstrom
510(k) history	9 submissions · 9 cleared · 2005-2022

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Msquared Associates, Inc.</b>
Contact	Cherita James

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211396/> 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 May 27, 2026