

K112679 SIMPLANT NAVIGATOR PERSONALIZED DENTAL CARE SYSTEMFeb 22, 2012
161 days to decisionK112679 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k112679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 14, 2011
Decision date	Feb 22, 2012
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Materialise Dental NV
Location	Leuven, BE
Contact	CARL VAN LIERDE
510(k) history	5 submissions · 5 cleared · 2008-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112679/>; 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 17, 2026