

K220577 Dental Handpiece, Model CA160, CA160L, and CA500LJul 29, 2022
151 days to decisionK220577 · Product code: **EGS** · Dental
Source: <https://www.510kdatabase.net/k220577/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Contra- And Right-angle Attachment, Dental (EGS)
Date received	Feb 28, 2022
Decision date	Jul 29, 2022
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Micro-Nx Co., Ltd.
Location	Daegu, KR
Contact	Sojeong Park
510(k) history	7 submissions · 7 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	K-Bio Solutions
Contact	Seohee Kwon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220577/> 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 25, 2026