

K203525 D functionMay 5, 2021
155 days to decisionK203525 · Product code: **NUW** · Dental
Source: <https://www.510kdatabase.net/k203525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, Dental (NUW)
Date received	Dec 1, 2020
Decision date	May 5, 2021
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ito Co., Ltd.
Location	Brookeville, MD, US
Contact	Takeshi Kobayashi
510(k) history	8 submissions · 8 cleared · 1999-2021

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