

K212049 Oclet TDS 1000Mar 8, 2022
251 days to decisionK212049 · Product code: **LFL** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k212049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Jun 30, 2021
Decision date	Mar 8, 2022
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tendonova Corporation
Location	Norcross, GA, US
Contact	Mark Samuels
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

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

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