

K182145 tün® ultrasonic tips product familyJun 7, 2019
303 days to decisionK182145 · Product code: **ELC** · Dental
Source: <https://www.510kdatabase.net/k182145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Aug 8, 2018
Decision date	Jun 7, 2019
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Engineered Endodontics
Location	Menomonee Falls, WI, US
Contact	Mark Fiorina
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Spectramedex, LLC
Contact	John Ziobro

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

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