

K191079 Piezon Built-in Kit, Piezon Built-in Kit LEDAug 16, 2019
115 days to decisionK191079 · Product code: **ELC** · Dental
Source: <https://www.510kdatabase.net/k191079/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Apr 23, 2019
Decision date	Aug 16, 2019
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	E.M.S Electro Medical Systems S.A
Location	North Attleboro, MA, US
Contact	Suzanne Fassio-Hardy
510(k) history	28 submissions · 28 cleared · 2005-2026

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