

K130137 BIOSONIC SUVI PIEZOELECTRIC SCALER AND POLISHER

Aug 23, 2013
217 days to decision

K130137 · Product code: ELC · Dental
Source: <https://www.510kdatabase.net/k130137/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Jan 18, 2013
Decision date	Aug 23, 2013
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coltene/Whaledent
Location	Cleveland, OH, US
Contact	EDWARD A KROLL
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k130137/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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