FDA 510(k) Premarket Notification

K132401 MEGA ISQ

CLEARED

Apr 9, 2014
251 days to decision

K132401 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k132401/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Aug 1, 2013
Decision date	Apr 9, 2014
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osstell AB**
Location	Alexandria, VA, US
Contact	CHERITA JAMES
510(k) history	4 submissions · 4 cleared · 2008-2019