FDA 510(k) Premarket Notification

K181888 Osstell Beacon

CLEARED

Aug 22, 2019
405 days to decision

K181888 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k181888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Jul 13, 2018
Decision date	Aug 22, 2019
Days to decision	405 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Msquared Associates, Inc.**
Contact	Cherita James

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