

K180527 IS3May 16, 2018
77 days to decisionK180527 · Product code: **EKX** · Dental
Source: <https://www.510kdatabase.net/k180527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Feb 28, 2018
Decision date	May 16, 2018
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hiossen, Inc.
Location	Fariless Hills, PA, US
Contact	David Kim
510(k) history	25 submissions · 25 cleared · 2009-2026

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