FDA 510(k) Premarket Notification

K180953 AnyCheck IMT-100

CLEARED

Feb 20, 2019
315 days to decision

K180953 · Product code: **EKX** · Dental
Source: https://www.510kdatabase.net/k180953/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Apr 11, 2018
Decision date	Feb 20, 2019
Days to decision	315 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dms Co., Ltd.**
Location	Wonju-Si, KR
Contact	Guntae Kim
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Allura Medical Solution, Inc.**
Contact	Hwi Joon Park

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