FDA 510(k) Premarket Notification

CLEARED

K181297 DENTIOIII series (DENTIOIII, DENTIOIII-S)

Nov 21, 2018
189 days to decision

K181297 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k181297/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	May 16, 2018
Decision date	Nov 21, 2018
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hdx Will Corp.**
Location	Cheongju-Si, KR
Contact	Lee Myoung-Joon
510(k) history	9 submissions · 9 cleared · 2016-2021