FDA 510(k) Premarket Notification

K191453 Cervitec F

CLEARED

Feb 11, 2020
256 days to decision

K191453 · Product code: **LBH** · Dental
Source: https://www.510kdatabase.net/k191453/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	May 31, 2019
Decision date	Feb 11, 2020
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ivoclar Vivadent, AG**
Location	Amherst, NY, US
Contact	Sandra Cakebread
510(k) history	31 submissions · 31 cleared · 2004-2022