FDA 510(k) Premarket Notification

K211916 IPS e.max One

CLEARED

Aug 20, 2021
60 days to decision

K211916 · Product code: **EIH** · Dental
Source: https://www.510kdatabase.net/k211916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jun 21, 2021
Decision date	Aug 20, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	**Ivoclar Vivadent, Inc.**
Contact	Anderjeet Gulati

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211916/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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