FDA 510(k) Premarket Notification

K163228 APVolution System

CLEARED

Jun 5, 2017
200 days to decision

K163228 · Product code: **EIH** · Dental
Source: https://www.510kdatabase.net/k163228/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Powder, Porcelain (EIH)
Date received	Nov 17, 2016
Decision date	Jun 5, 2017
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesthetic-Press, LLC**
Location	New Port Richey, FL, US
Contact	Jorg Muller
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k163228/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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