FDA 510(k) Premarket Notification

K240888 Calibra Abutment Resin Cement

CLEARED

Apr 2, 2024
1 days to decision

K240888 · Product code: **EMA** · Dental
Source: https://www.510kdatabase.net/k240888/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cement, Dental (EMA)
Date received	Apr 1, 2024
Decision date	Apr 2, 2024
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dentsply Sirona**
Location	York, PA, US
Contact	Rebecca Sporer
Website	https://www.dentsplysirona.com
510(k) history	65 submissions · 65 cleared · 2016-2026

Dentsply Sirona is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company markets products in over 120 countries and operates factories across 21 nations. Dentsply Sirona has received FDA 510(k) clearances from total submissions since 2016. Dental devices represent 78% of the company's regulatory submissions, reflecting its core focus on laboratory equipment, specialty products, and consumables including abutments, CAD/CAM blocks, and restorative materials. The company's latest clearance in 2026 demonstrates continued reg...

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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