FDA 510(k) Premarket Notification

K221381 KDG Abutments

CLEARED

Aug 10, 2022
89 days to decision

K221381 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k221381/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 13, 2022
Decision date	Aug 10, 2022
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Keystone Dental, Inc.**
Location	San Diego, CA, US
Contact	Nancy DeAngelo
510(k) history	7 submissions · 7 cleared · 2007-2024

REGULATORY CONSULTANT

Consulting firm	**Aclivi, LLC**
Contact	Chris Brown

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

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Device record: https://www.510kdatabase.net/k221381/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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