FDA 510(k) Premarket Notification

CLEARED

K250473 Dental Delivery System Series 5 and Dental Delivery System Series 5 Plus

Feb 19, 2025

K250473 · Product code: **EIA** · Dental
Source: https://www.510kdatabase.net/k250473/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Feb 19, 2025
Decision date	Feb 19, 2025
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Dci International, LLC**
Location	Newberg, OR, US
Contact	Dana Shusterman
510(k) history	1 submissions · 1 cleared · 2025-2025

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