FDA 510(k) Premarket Notification

K203701 Locator Overdenture Implant System

CLEARED

Apr 15, 2021
118 days to decision

K203701 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k203701/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 18, 2020
Decision date	Apr 15, 2021
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ivory Super Holdco Inc. / Zest Anchors, LLC**
Location	Carlsbad, CA, US
Contact	Marysa Loustalot
510(k) history	1 submissions · 1 cleared · 2021-2021