FDA 510(k) Premarket Notification

K200817 URIS OMNI Narrow System & Prosthetic

CLEARED

Oct 7, 2020
191 days to decision

K200817 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k200817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 30, 2020
Decision date	Oct 7, 2020
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Truabutment, Inc.**
Location	Anaheim, CA, US
Contact	Eunjin Jang
510(k) history	15 submissions · 15 cleared · 2018-2025