FDA 510(k) Premarket Notification

K102822 IMPLANT-ONE SYSTEM

CLEARED

Jan 10, 2011
104 days to decision

K102822 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k102822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 28, 2010
Decision date	Jan 10, 2011
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Custom Dental Implants, Inc.**
Location	Chseterland, OH, US
Contact	KAREN E WARDEN
510(k) history	1 submissions · 1 cleared · 2011-2011