FDA 510(k) Premarket Notification

K103537 ET III SA ULTRA WIDE SYSTEM

CLEARED

Mar 10, 2011
98 days to decision

K103537 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k103537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 2, 2010
Decision date	Mar 10, 2011
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hiossen, Inc.**
Location	Fariless Hills, PA, US
Contact	PATRICK LIM
510(k) history	26 submissions · 26 cleared · 2009-2026