FDA 510(k) Premarket Notification

K133049 3I T3(R) EXTERNAL HEX DENTAL IMPLANTS

CLEARED

Jan 8, 2014
103 days to decision

K133049 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k133049/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 27, 2013
Decision date	Jan 8, 2014
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet 3i**
Location	Palm Beach Gardens, FL, US
Contact	CHRIS MCKEE
510(k) history	12 submissions · 12 cleared · 2007-2019