FDA 510(k) Premarket Notification

K171185 IR Type Implant System

CLEARED

Dec 1, 2017
221 days to decision

K171185 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k171185/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 24, 2017
Decision date	Dec 1, 2017
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biotem Co., Ltd.**
Location	Busan, KR
Contact	Hong Koo Yeo
510(k) history	6 submissions · 6 cleared · 2017-2023