FDA 510(k) Premarket Notification

K173938 IS-III HActive Fixture

CLEARED

May 24, 2018
149 days to decision

K173938 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k173938/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 26, 2017
Decision date	May 24, 2018
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neobiotech Co., Ltd.**
Location	Santa Fe Springs, CA, US
Contact	Young-Ko Heo
510(k) history	17 submissions · 17 cleared · 2004-2024