FDA 510(k) Premarket Notification

K173141 CSM Submerged3-L Implant System

CLEARED

Sep 19, 2018
355 days to decision

K173141 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k173141/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 29, 2017
Decision date	Sep 19, 2018
Days to decision	355 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Csm Implant**
Location	Brea, CA, US
Contact	Sung Am Cho
510(k) history	3 submissions · 3 cleared · 2011-2018

REGULATORY CONSULTANT

Consulting firm	**Withus Group, Inc.**
Contact	April Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov