FDA 510(k) Premarket Notification

K192062 Nucleoss T6 Dental Implant System

CLEARED

Aug 27, 2020
392 days to decision

K192062 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k192062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 1, 2019
Decision date	Aug 27, 2020
Days to decision	392 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sanlilar Tibbi Cihazlar Medikal Kimya Sanayi Ticaret Ltd. ST**
Location	Izmir, TR
Contact	Ezgi Ozbudak
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Cardiomed Device Consultants**
Contact	Semih Oktay

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k192062/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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