FDA 510(k) Premarket Notification

CLEARED

K190192 K3Pro Konus New Abutments and Implants

Feb 10, 2020
371 days to decision

K190192 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k190192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 4, 2019
Decision date	Feb 10, 2020
Days to decision	371 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Argon Med. Productions Vertriebs Gesellschaft Mbh CO KG**
Location	Bingen Am Rhein, DE
Contact	Richard Donaca
510(k) history	3 submissions · 3 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	**Argon Dental USA, LLC**
Contact	Celline Lakus

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