FDA 510(k) Premarket Notification

K183438 Geomed Vascular Dilators

CLEARED

Sep 3, 2019
265 days to decision

K183438 · Product code: **DWP** · Cardiovascular
Source: https://www.510kdatabase.net/k183438/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, Surgical (DWP)
Date received	Dec 12, 2018
Decision date	Sep 3, 2019
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Geomed Medizin-Technik GmbH & Co.**
Location	Amsterdam, Nh, NL
Contact	Hanno Haug
510(k) history	2 submissions · 2 cleared · 2005-2019

REGULATORY CONSULTANT

Consulting firm	**Business Support International**
Contact	Angelika Scherp

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