

**K183438 Geomed Vascular Dilators**Sep 3, 2019  
265 days to decisionK183438 · 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	<b>Geomed Medizin-Technik GmbH &amp; Co.</b>
Location	Amsterdam, Nh, NL
Contact	Hanno Haug
510(k) history	2 submissions · 2 cleared · 2005-2019

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Business Support International</b>
Contact	Angelika Scherp

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183438/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 20, 2026