

K201279 ASSISTO Universal Applicator Clamping DeviceJul 10, 2020
58 days to decisionK201279 · Product code: **JAQ** · Radiology
Source: <https://www.510kdatabase.net/k201279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	May 13, 2020
Decision date	Jul 10, 2020
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Geomed Medizin-Technik GmbH & Co. KG
Location	Wumlingen, DE
Contact	Hanno Haug
510(k) history	2 submissions · 2 cleared · 2010-2020

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](https://accessdata.fda.gov)

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