

**K202112 Storz Medical Duolith SD1 T-Top & Tower System with C-Actor Sepia Handpiece**Feb 21, 2021  
206 days to decision

K202112 · Product code: PZL · General &amp; Plastic Surgery

Source: <https://www.510kdatabase.net/k202112/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal Shock Wave Device For Treatment Of Diabetic Foot Ulcers (PZL)
Date received	Jul 30, 2020
Decision date	Feb 21, 2021
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Storz Medical AG</b>
Location	Tagerwilen, CH
Contact	Pavel Novak
510(k) history	3 submissions · 3 cleared · 2018-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biomed Research, Inc.</b>
Contact	Michael Dayton

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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510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202112/> 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 May 26, 2026