

K223629 SpiroSphere, SpiroSphereECG, CardioSphereMay 28, 2024
540 days to decisionK223629 · Product code: **BTY** · Cardiovascular
Source: <https://www.510kdatabase.net/k223629/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Dec 5, 2022
Decision date	May 28, 2024
Days to decision	540 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eresearchtechnology GmbH
Location	Estenfeld, DE
Contact	Kristin Feld
510(k) history	3 submissions · 3 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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.netDevice record: <https://www.510kdatabase.net/k223629/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026