

K173937 SpiroSphereFeb 15, 2019
416 days to decisionK173937 · Product code: **BTY** · Anesthesiology
Source: <https://www.510kdatabase.net/k173937/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Dec 26, 2017
Decision date	Feb 15, 2019
Days to decision	416 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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