FDA 510(k) Premarket Notification

CLEARED

K192092 Seca Medical Vital Signs Analyzer 535, Seca mVSA 535, Seca mVSA, Seca 535

Jan 23, 2020
171 days to decision

K192092 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k192092/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Aug 5, 2019
Decision date	Jan 23, 2020
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Seca GmbH & Co. KG**
Location	Washington, DC, US
Contact	Corinna Hatje
510(k) history	2 submissions · 2 cleared · 2013-2020

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Oliver Eikenberg

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