

K193138 Colibri SystemDec 27, 2021
775 days to decisionK193138 · Product code: **QQV** · Microbiology
Source: <https://www.510kdatabase.net/k193138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated System For Sample Preparation And Identification Of Microorganisms From Cultured Isolates By Mass Spectrometry (QQV)
Date received	Nov 13, 2019
Decision date	Dec 27, 2021
Days to decision	775 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Copan Wasp Srl
Location	Brescia, IT
Contact	Catalano Giovanna
510(k) history	5 submissions · 5 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Studio D&apos;Ingegneria Enrico Bisson
Contact	Bisson Enrico

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

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