

K250395 BioBrace ® RC Delivery SystemApr 7, 2025
54 days to decisionK250395 · Product code: **ORQ** · Orthopedic
Source: <https://www.510kdatabase.net/k250395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Deployer (ORQ)
Date received	Feb 12, 2025
Decision date	Apr 7, 2025
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Conmed Corporation
Location	Utica, NY, US
Contact	Dionne Sanders
510(k) history	82 submissions · 82 cleared · 2004-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250395/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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