

K203267 The BioBrace ImplantApr 30, 2021
176 days to decisionK203267 · Product code: **OWW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k203267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement Of Tendon (OWW)
Date received	Nov 5, 2020
Decision date	Apr 30, 2021
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biorez, Inc.
Location	New Haven, CT, US
Contact	Kevin Rocco
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	BioVera, Inc.
Contact	Robert A Poggie

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

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