FDA 510(k) Premarket Notification

# K203267 The BioBrace Implant

**CLEARED**

Apr 30, 2021
176 days to decision

K203267 · 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