

**K210298 GR-14 Resin System**May 5, 2021  
91 days to decisionK210298 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k210298/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI) |
| Date received         | Feb 3, 2021   |
| Decision date         | May 5, 2021   |
| Days to decision      | 91 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Pro3dure Medical GmbH</b>          |
| Location       | Iserlohn, DE                          |
| Contact        | Frank Gischer                         |
| 510(k) history | 4 submissions · 4 cleared · 2020-2022 |

**REGULATORY CONSULTANT**

---

|                 |  |
|-----------------|--|
| Consulting firm | <b>Regulatory and Quality Solutions, LLC</b> |
| Contact         | Patricia Kontoudis                           |

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210298/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026