

K193212 DSM Biomedical Dental Bone Graft PlusSep 10, 2020
294 days to decisionK193212 · Product code: **NPM** · Dental
Source: <https://www.510kdatabase.net/k193212/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bone Grafting Material, Animal Source (NPM) |
| Date received | Nov 21, 2019 |
| Decision date | Sep 10, 2020 |
| Days to decision | 294 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dsm Biomedical |
| Location | Exton, PA, US |
| Contact | Susan Pileggi |
| 510(k) history | 3 submissions · 3 cleared · 2015-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193212/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026