

**K150079 Regenomer® Syringe, Regenomer® Plug,
Regenomer® Block**Dec 10, 2015
329 days to decisionK150079 · Product code: **NPM** · Dental
Source: <https://www.510kdatabase.net/k150079/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Bone Grafting Material, Animal Source (NPM) |
| Date received | Jan 15, 2015 |
| Decision date | Dec 10, 2015 |
| Days to decision | 329 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Nibec Co., Ltd. |
| Location | Los Angeles, CA, US |
| Contact | YOON-JEONG PARK |
| 510(k) history | 3 submissions · 3 cleared · 2014-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150079/>; 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 June 3, 2026