

K190871 Bio-TackS Orthodontic Mini ImplantJan 17, 2020
289 days to decisionK190871 · Product code: **OAT** · Dental
Source: <https://www.510kdatabase.net/k190871/>**SUBMISSION DETAILS**

| | |
|-----------------------|----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Orthodontic (OAT) |
| Date received | Apr 3, 2019 |
| Decision date | Jan 17, 2020 |
| Days to decision | 289 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biocetec Co., Ltd. |
| Location | Seoul, KR |
| Contact | Hee Sue Jin |
| 510(k) history | 4 submissions · 4 cleared · 2017-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190871/> 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 26, 2026