

K241032 BellaTek BarsJul 15, 2024
90 days to decisionK241032 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k241032/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received | Apr 16, 2024 |
| Decision date | Jul 15, 2024 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biomet 3i, LLC |
| Location | Palm Beach Gardens, FL, US |
| Contact | Krupal Patel |
| 510(k) history | 7 submissions · 7 cleared · 2019-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Michael Davis Quality and Regulatory Consulting, LLC |
| Contact | Michael Davis |

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