

K203344 Premilled Titanium Block SystemAug 25, 2021
285 days to decisionK203344 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k203344/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Abutment, Implant, Dental, Endosseous (NHA) |
| Date received | Nov 13, 2020 |
| Decision date | Aug 25, 2021 |
| Days to decision | 285 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Innobiosurg Co., Ltd. |
| Location | Echo, AZ, US |
| Contact | Sun-Mi Park |
| 510(k) history | 15 submissions · 15 cleared · 2015-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|---------------------------|
| Consulting firm | Withus Group, Inc. |
| Contact | April Lee |

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

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