

K193234 NUVO IF Implant SystemJun 18, 2020
206 days to decisionK193234 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k193234/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Nov 25, 2019 |
| Decision date | Jun 18, 2020 |
| Days to decision | 206 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Jjgc Industria E Comercio DE Materiais Dentarios S.A. |
| Location | Curitiba, BR |
| Contact | Luiza Vaccari Toppel |
| 510(k) history | 28 submissions · 28 cleared · 2016-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|---------------------------|
| Consulting firm | Straumann USA, LLC |
| Contact | Jennifer M. Jackson |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193234/> 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 28, 2026