FDA 510(k) Premarket Notification

# K182620 MRI Compatibility for Existing Neodent Implant System

**CLEARED**

Jan 18, 2019
116 days to decision

K182620 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k182620/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Sep 24, 2018 |
| Decision date | Jan 18, 2019 |
| Days to decision | 116 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

## APPLICANT

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

## REGULATORY CONSULTANT

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|---|---|
| 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