

K190665 Neodent Instrument Kit CasesDec 23, 2019
283 days to decisionK190665 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k190665/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT) |
| Date received | Mar 15, 2019 |
| Decision date | Dec 23, 2019 |
| Days to decision | 283 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190665/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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