

K212404 S.I.N. Instrument KitsNov 3, 2021
93 days to decisionK212404 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k212404/>**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 | Aug 2, 2021 |
| Decision date | Nov 3, 2021 |
| Days to decision | 93 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | S.I.N. ? Sistema DE Implante Nacional S.A. |
| Location | Sao Paulo, BR |
| Contact | Denise Domiciano |
| 510(k) history | 17 submissions · 17 cleared · 2017-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------------------|
| Consulting firm | PaxMed International, LLC |
| Contact | Kevin A. Thomas |

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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