

K213823 Intera Refill KitMar 16, 2022
98 days to decisionK213823 · Product code: **PTI** · General Hospital
Source: <https://www.510kdatabase.net/k213823/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Non-coring (huber) Needle (PTI) |
| Date received | Dec 8, 2021 |
| Decision date | Mar 16, 2022 |
| Days to decision | 98 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Intera Oncology, Inc. |
| Location | Wellesley, MA, US |
| Contact | Michael Gaisford |
| 510(k) history | 2 submissions · 2 cleared · 2021-2022 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Heyer Regulatory Solutions, LLC |
| Contact | Sheila Hemeon-Heyer |

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/k213823/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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