

**K211121 Intera Non-coring (Huber) Refill Needles, Intera Non-coring (Huber) Special bolus Needles and OR Prep Kit**Oct 14, 2021  
182 days to decisionK211121 · Product code: PTI · General Hospital  
Source: <https://www.510kdatabase.net/k211121/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-coring (huber) Needle (PTI)
Date received	Apr 15, 2021
Decision date	Oct 14, 2021
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Heyer Regulatory Solutions, LLC</b>
Contact	Sheila Hemeon-Heyer

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211121/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026