

**K243711 Confocal Microprobe Imaging System (BrightP980)**Jul 24, 2025  
234 days to decisionK243711 · Product code: **OWN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k243711/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Dec 2, 2024
Decision date	Jul 24, 2025
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Confocal Microprobe Imaging System (BrightP960); Confocal Microprobe Imaging System (BrightP880); Confocal Microprobe Imaging System (BrightP860); Confocal Microprobe Imaging System (BrightP780); Confocal Microprobe Imaging System (BrightP750); Confocal Microprobe Imaging System (BrightP680); Confocal Microprobe Imaging System (BrightP660); Confocal Microprobe Imaging System (BrightP600); Confocal Microprobe Imaging System (BrightP580);

**APPLICANT**

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Company	<b>Wuxi Hisky Medical Technologies Co., Ltd.</b>
Location	Wuxi, CN
Contact	Jinhua Shao
510(k) history	5 submissions · 5 cleared · 2018-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Pureid Medical Technology Co., Ltd.</b>
Contact	Jarvis Wu

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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