

**K232240 Microwave Ablation System (BD-GT)**Nov 13, 2023  
108 days to decisionK232240 · Product code: **NEY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k232240/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Ablation, Microwave And Accessories (NEY) |
| Date received         | Jul 28, 2023                                      |
| Decision date         | Nov 13, 2023                                      |
| Days to decision      | 108 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|--|
| Company        | <b>Betters(Suzhou) Medical Co., Ltd.</b> |
| Location       | Suzhou, CN                               |
| Contact        | Lei Liu                                  |
| 510(k) history | 2 submissions · 2 cleared · 2023-2023    |

**REGULATORY CONSULTANT**

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|-----------------|---|
| Consulting firm | <b>APlus Healthcare Technology (Shanghai) Co., Ltd.</b> |
| Contact         | Ada Wang  |

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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