

**K192970 SLIMUS**Dec 1, 2020  
405 days to decisionK192970 · Product code: **PKT** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k192970/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Traditional   |
| Device classification | Laser For Disruption Of Adipocyte Cells For Aesthetic Use (PKT) |
| Date received         | Oct 23, 2019  |
| Decision date         | Dec 1, 2020   |
| Days to decision      | 405 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Hironic Co., Ltd.</b>              |
| Location       | Gyeonggi-Do, KR                       |
| Contact        | Duk Ho Kong                           |
| 510(k) history | 8 submissions · 8 cleared · 2018-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192970/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026