

K183020 Endosee SystemJan 31, 2019
91 days to decisionK183020 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k183020/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hysteroscope (and Accessories) (HIH) |
| Date received | Nov 1, 2018 |
| Decision date | Jan 31, 2019 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | CooperSurgical, Inc. |
| Location | Mountain View, CA, US |
| Contact | Roaida Johnson |
| 510(k) history | 41 submissions · 40 cleared · 1991-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183020/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026