

K111760 NAVIAID(TM) BGC DEVICEAug 9, 2011
48 days to decisionK111760 · Product code: **ODC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k111760/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Endoscope Channel Accessory (ODC) |
| Date received | Jun 22, 2011 |
| Decision date | Aug 9, 2011 |
| Days to decision | 48 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Smart Medical Systems , Ltd. |
| Location | Kfar Saba, IL |
| Contact | ADVA YOSELZON |
| 510(k) history | 9 submissions · 9 cleared · 2006-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111760/> 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 27, 2026