

K011652 BODY FAT ANALYZER, MODEL HBF-306Nov 7, 2001
162 days to decisionK011652 · Product code: **MNW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011652/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Analyzer, Body Composition (MNW) |
| Date received | May 29, 2001 |
| Decision date | Nov 7, 2001 |
| Days to decision | 162 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Omron Healthcare, Inc. |
| Location | Vernon Hills, IL, US |
| Contact | OSAMU SHIRASAKI |
| 510(k) history | 68 submissions · 67 cleared · 1991-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011652/> 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 June 28, 2026