

K081881 GISH TUBING AND CONNECTORS WITH HA COATINGJan 23, 2009
205 days to decisionK081881 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k081881/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF) |
| Date received | Jul 2, 2008 |
| Decision date | Jan 23, 2009 |
| Days to decision | 205 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Gish Biomedical, Inc. |
| Location | Mchenry, IL, US |
| Contact | EDWARD F WADDELL |
| 510(k) history | 75 submissions · 75 cleared · 1983-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081881/> 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 26, 2026