

K083349 BLOOD TRANSFUSION SETApr 10, 2009
148 days to decisionK083349 · Product code: **BRZ** · General Hospital
Source: <https://www.510kdatabase.net/k083349/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Blood Transfusion (BRZ) |
| Date received | Nov 13, 2008 |
| Decision date | Apr 10, 2009 |
| Days to decision | 148 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shan Dong Wei Gao Group Medical Polymer Products |
| Location | Shan Nan Er Rd., Shanghai, CN |
| Contact | Diana Hong |
| 510(k) history | 3 submissions · 3 cleared · 2009-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083349/> 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 22, 2026