

K915546 PS MEDICAL VENTRICULOSTOMY KITDec 30, 1991
19 days to decisionK915546 · Product code: **HBG** · Neurology
Source: <https://www.510kdatabase.net/k915546/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Drills, Burrs, Trephines & Accessories (manual) (HBG) |
| Date received | Dec 11, 1991 |
| Decision date | Dec 30, 1991 |
| Days to decision | 19 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|----------------------------------------------|
| Company | Pudenz-Schulte Medical Research Corp. |
| Location | Mchenry, IL, US |
| Contact | TOM HOLDYCH |
| 510(k) history | 40 submissions · 39 cleared · 1980-1996 |

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