

K802913 TAN DEM* - IGE KITMay 29, 1981
192 days to decisionK802913 · Product code: **DGC** · Chemistry
Source: <https://www.510kdatabase.net/k802913/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ige, Antigen, Antiserum, Control (DGC) |
| Date received | Nov 18, 1980 |
| Decision date | May 29, 1981 |
| Days to decision | 192 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Hybritech, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 63 submissions · 63 cleared · 1981-1997 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802913/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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