FDA 510(k) Premarket Notification

# K051282 VENTANA IMAGE ANALYSIS SYSTEM - HER2/NEU

**CLEARED**

Aug 16, 2005
91 days to decision

K051282 · Product code: **NOT** · Pathology
Source: https://www.510kdatabase.net/k051282/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Date received | May 17, 2005 |
| Decision date | Aug 16, 2005 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Tripath Imaging, Inc.** |
| Location | Burlington, NC, US |
| Contact | BRYAN J TUCKER |
| 510(k) history | 4 submissions · 4 cleared · 2005-2006 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k051282/ 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 14, 2026