

K090753 THERATEST EL-ANTI-CCP/2Mar 5, 2010
350 days to decisionK090753 · Product code: **NHX** · Immunology
Source: <https://www.510kdatabase.net/k090753/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX) |
| Date received | Mar 20, 2009 |
| Decision date | Mar 5, 2010 |
| Days to decision | 350 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Theratest Laboratories, Inc. |
| Location | Chicago, IL, US |
| Contact | MARIUS TEODORESCU |
| 510(k) history | 22 submissions · 22 cleared · 1991-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090753/> 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 21, 2026