**CLEARED**

Feb 28, 2023
267 days to decision

# K221641 Terragene® Bionova® Hyper Biological Indicator (BT98), Terragene® Bionova® Hyper Auto-reader Incubator (BHY), Terragene® Bionova® NanoBio Auto-reader Incubator (BNB)

K221641 · Product code: **FRC** · General Hospital
Source: https://www.510kdatabase.net/k221641/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator, Biological Sterilization Process (FRC) |
| Date received | Jun 6, 2022 |
| Decision date | Feb 28, 2023 |
| Days to decision | 267 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Terragene S.A.** |
| Location | Rosario, AR |
| Contact | Hernando Carrizo |
| 510(k) history | 8 submissions · 7 cleared · 2017-2024 |