
510(k) Summary

1. General Information 21 CFR 807.92(a)(1)

Submitter: Life Technologies Corporation
9099 North Deerbrook Trail
Brown Deer, WI 53223

Manufacturer: Applied Biosystems B.V a part of Life Technologies Corporation
Blk 33, #05-03 Marsiling Industrial Estate Road 3
Singapore 739256

Contact: Dr. Kelli Tanzella
Director, Americas Regulatory Affairs

Phone: 716-774-3122

Fax: 716-774-6996

E-mail: kelli.tanzella@lifetech.com

2. Name of Device and Classification – 21 CFR 807.92(a)(2)

Trade Name/Common Name: 3500 Dx / 3500 xL Dx Genetic Analyzer CS2 and 3500 Dx Series Data Collection Software

Classification: Class II

Product Code: NSU, Instrumentation for clinical multiplex systems

3. Predicate Device – 21 CFR 807.92(a)(3):

| Manufacturer | Product Name | 510(k) No. |
|--|---|------------|
| Applied Biosystems (aka Life Technologies Corporation) | Applied Biosystems 7500 Fast Dx Real Time PCR | K082562 |
| Celera Diagnostics | ViroSeq HIV-1 Genotyping System with the 3100 Genetic Analyzer, | BK030005 |

4. Device Description – 21 CFR 807.92(a)(4)

The 3500 Dx / xL Dx Genetic Analyzer CS2 is a fluorescence based DNA analysis instrument using capillary electrophoresis technology with 8 or 24-capillaries suitable for the detection and electrophoretic analysis of DNA fragments.

The 3500 Dx / xL Dx Genetic Analyzer CS2 is configured as either a low throughput (8 capillaries) or medium throughput (24 capillaries; xL indicates medium throughput version with 24 capillaries) instrument. The 3500 Dx Series Data Collection Software provides control and monitoring of the instrument, collection of data during an injection, and primary analysis of injection data.

The software provides three main functions:

- Facilitates creation of the information used by the instrument to perform the injection and by primary analysis to perform data reduction.
- Communicates with the instrument to provide injection parameters and retrieve both raw instrument data and general instrument status.
- Provides data reduction of instrument data for storage in sample files. These files are then used by a secondary analysis application (i.e. uTYPE[®] Dx) to provide specific results.

The following consumables (branded with the Applied Biosystems name) are required to operate the 3500 Dx / xL Dx Genetic Analyzer CS2. These consumables are manufactured in accordance with GMP requirements:

- Capillaries enable the labeled DNA fragments to migrate from the cathode toward the anode for sequencing detection.
- POP Polymers (i.e. POP-6[™]) are used as separation matrices for generating electropherogram data from the 3500 Dx/ xL Dx Genetic Analyzer CS2.
- Hi-Di[™] Formamide is a sample re-suspension solution used for electrokinetic injection.
- BigDye[®] Terminator (BDT) v1.1 Sequencing Standard is used for instrument and spectral calibrations.
- Cathode Buffer Container is pre-filled with buffer and supports electrophoresis.
- Anode Buffer Container is pre-filled with buffer and maintains a source of ions and the correct pH for electrophoresis.
- Conditioning Reagent is a pre-filled pouch used for priming the polymer pump, washing the pump between polymer type changes, and during instrument shutdown.

5. Intended Use/Indications for Use – 21 CFR 807.92(a)(5)

The Applied Biosystems[®] 3500 Dx / 3500xL Dx Genetic Analyzer CS2 with 3500 Dx Series Software 2011 (v1) are in vitro diagnostic devices intended for the sequencing (detection and identification) of fluorescently-labeled deoxyribonucleic acid (DNA) by capillary electrophoresis.

The Applied Biosystems[®] 3500 Dx / 3500xL Dx Genetic Analyzer CS2 with 3500 Dx Series Software 2011 (v1) are indicated for use with FDA-cleared or approved

sequencing assays specifying their use and only by technologists trained in laboratory techniques, procedures, and use of the analyzer.

6. Performance Data – 21 CFR 807.92(b)

Analytical and clinical performance of the 3500 Dx / 3500xL Dx Genetic Analyzer CS2 with 3500 Dx Series Software is assessed for each assay to be run on this system.

The SeCore[®] HLA Sequencing System and uTYPE[®] Dx v1.0 HLA Sequence Analysis Software is being submitted separately, but concurrent with this instrument submission.

Please refer to the SeCore[®] HLA Sequencing System assay 510(k) submission, BK110038 for the analytical and clinical testing which includes the following:

- Interference
- Detection limit
- Design verification (guard-banding) studies
- Precision,
- Multi-center reproducibility
- Lot-to-lot reproducibility

Shipping and Stability Studies:

Results of real time stability studies for 3500 Dx / 3500xL Dx Genetic Analyzer CS2 consumables demonstrated consumable stability and container integrity for all finished goods through the expiry dates noted on the packaging. The following consumables are stable through their respective labeled expiry dates: POP-6[™] @ 2-8°C for 9 months, BigDye[®] Terminator (BDT) v1.1 Sequencing Standard @ -20°C for 21 months, Cathode Buffer Container and Anode Buffer Container @ 2-8°C for 12 months, and Conditioning Reagent @ 2-8°C for 9 months. Testing was verified through accelerated, real time, open pack, and transport stability studies in accordance with EN13640:2002.