February 21, 2020

Life Technologies Corporation
Darcie Baynes
Regulatory Affairs Specialist
5781 Van Allen Way
Carlsbad, CA 92008

Re: k191030
Trade/Device Name: Applied Biosystems™ 3500 Dx Genetic Analyzer and Applied Biosystems™ 3500xL Dx Genetic Analyzer
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation For Clinical Multiplex Test Systems
Regulatory Class: Class II exempt, meets the limitation of exemptions 21 CFR 862.9(a)
Product Code: PCA
Dated: February 3, 2020
Received: February 4, 2020

Dear Darcie Baynes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 862.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 862.9.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191030

Device Name
Applied Biosystems™ 3500 Dx Genetic Analyzer
and
Applied Biosystems™ 3500xL Dx Genetic Analyzer

Indications for Use *(Describe)*
The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer are in vitro diagnostic devices intended for detection of fluorescently-labeled human genomic deoxyribonucleic acid (DNA) nucleotides by capillary electrophoresis.

The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer are indicated for sequencing and fragment analysis using FDA- cleared or approved assays.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Information - 21 CFR 807.92(a)(1):

Submitter:	Life Technologies Corporation 5781 Van Allen Way Carlsbad, CA 92008
Manufacturer:	Life Technologies Holdings Pte Ltd Blk 33, #07-06, Marsiling Industrial Estate, Road 3 Singapore 739256
Establishment Registration No:	3003673482
510(k) Number	K191030
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Date Prepared:	February 18, 2020

Device Name - 21 CFR 807.92(a)(2):

Device Name:	Applied Biosystems™ 3500 Dx Genetic Analyzer and Applied Biosystems™ 3500xL Dx Genetic Analyzer
Common Name:	DNA Genetic Analyzer
Classification:	Class II, exempt from the premarket notification requirement subject to the limitations in 21 CFR 862.9
Product Code:	PCA

Predicate Device 21 CFR 807.92(a)(3)

Predicate	Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzer CS2 and 3500 Dx Series Software, BK110039

Device Description 21 CFR 807.92(a)(4):

The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer are fluorescence-based DNA analysis instruments that use capillary electrophoresis technology with 8 and 24 capillaries, respectively.

The 8-capillary system and the 24-capillary system include the following components:

- 8-capillary or 24-capillary array and POP™ polymer
- Consumables for system qualification
- Computer workstation and monitor
- Integrated software for instrument control, data collection, quality control, basecalling and sizecalling of samples

The following consumables (branded with the Applied Biosystems name) are required to operate the Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer.

- 50cm Capillary Array: enable the labeled DNA fragments to migrate from the cathode toward the anode for detection
- POP-6™ Polymer: used as a separation matrix to separate DNA fragments by size during electrophoresis for sequencing
- POP-7™ Polymer: used as a separation matrix for separating DNA fragments by size during electrophoresis for fragment analysis
- Hi-Di™ Formamide: sample re-suspension solution used for electrokinetic injection and denaturing the DNA
- Sequencing Standard v1.1: used for spectral calibration of the instrument and instrument performance check
- Cathode Buffer Container: pre-filled with running buffer which maintains a source of ions and the correct pH for electrophoresis
- Anode Buffer Container: pre-filled with running buffer which maintains a source of ions and the correct pH for electrophoresis
- Conditioning Reagent: pre-filled pouch used for priming the polymer pump, washing the pump between polymer type changes, and during instrument shutdown
- DS-30 Matrix Standard – Dx: used for spectral calibration
- DS-33 Matrix Standard – Dx: used for spectral calibration
- DS-33 GeneScan™ Install Kit – Dx: used for instrument operational qualification
- GeneScan™ 600 LIZ® Size Standard v2.0 – Dx: used as a ladder for sizing DNA fragments
- Other accessories (e.g. sample plate holders, plate retainers, septa)

Intended Use 21 CFR 807.95(a)(5):

The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer are in vitro diagnostic devices intended for detection of fluorescently-labeled human genomic deoxyribonucleic acid (DNA) nucleotides by capillary electrophoresis.

The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer are indicated for sequencing and fragment analysis using FDA- cleared or approved assays.

Predicate Device Comparison 21 CFR 807.92(a)(6):

A summary of the technological characteristics of the device compared to the predicate device is provided. The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer and the legally marketed device the Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzer CS2 and 3500 Dx Series Software are compared in the table below.

Feature	**Applied Biosystems 3500 Dx/3500xL Dx CS2 and 3500 Dx Series Software (BK110039)**	**Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer (with Fragment Analysis)**	**Comparison**
510k number	BK110039	K191030	N/A
Regulation	862.2570	862.2570	Same
Product Code	PCA	PCA	Same
Device Class	Class II	Class II	Same
Intended Use	The Applied Biosystems® 3500 Dx / 3500xL Dx Genetic Analyzer CS2 and 3500 Dx Series Software are in vitro diagnostic devices intended for the sequencing (detection and identification) of fluorescently-labeled deoxyribonucleic	The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer are in vitro diagnostic devices intended for detection of fluorescently-labeled human genomic	Software upgrade to Data Collection Software (DCS) 3 IVD v3.2 and enablement of Fragment Analysis in Diagnostic mode.

Feature	Applied Biosystems 3500 Dx/3500xL Dx CS2 and 3500 Dx Series Software (BK110039)	Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer (with Fragment Analysis)	Comparison
	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.	deoxyribonucleic acid (DNA) nucleotides by capillary electrophoresis. The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer are indicated for sequencing and fragment analysis using FDA- cleared or approved assays.	
Data Collection Software	3500 Dx Data Collection Software 2011 v1.01	Applied Biosystems™ 3500 Dx Series Data Collection Software 3 IVD v3.2	Upgrade to Data Collection Software 3 IVD v3.2
Firmware	6228001-05	6228001-05	Same
Computer	Dell OptiPlex XE	Dell OptiPlex XE2	Upgrade to new model.
Windows	Windows® 7	Windows® 7	Same
Laser	Single-line 505 nm, solid-state	Single-line 505 nm, solid-state	Same

Feature	Applied Biosystems 3500 Dx/3500xL Dx CS2 and 3500 Dx Series Software (BK110039)	Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer (with Fragment Analysis)	Comparison
Electrophoresis Voltage	Up to 20Kv	Up to 20Kv	Same
Oven Temperature	18°C to 70°C	18°C to 70°C	Same
Operating Environment	Temperature: 15°C–30°C	Temperature: 15°C–30°C	Same
	Humidity: 20–80% (non-condensing)	Humidity: 20–80% (non-condensing)	Same
Main Power Voltage	100–240 V ±10%; 50–60 Hz	100–240 V ±10%; 50–60 Hz	Same
Power Consumption	320 VA	320VA	Same
Dimensions (Width x Depth x Height)	61cm(122cm) x 61cm x 72cm	61cm(122cm) x 61cm x 72cm	Same
Weight	82Kg	82Kg	Same
Polymer Use	POP-6™ Dx	POP-6™ Dx and POP-7™ Dx	Inclusion of POP-7 for Fragment Analysis application in IVD mode of proposed device.
Capillary Array	50 cm length available in 8-capillary and 24 capillary configuration	50 cm length available in 8-capillary and 24 capillary configuration	Same, however the 50 cm array will be used for fragment analysis workflow in IVD mode.
Applications	Sequencing and Fragment Analysis in RUO mode, Sequencing in IVD mode	Sequencing and Fragment Analysis in RUO mode, Sequencing and Fragment Analysis in IVD mode	Inclusion of Fragment Analysis application in IVD mode of proposed device.

Feature	**Applied Biosystems 3500 Dx/3500xL Dx CS2 and 3500 Dx Series Software (BK110039)**	**Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer (with Fragment Analysis)**	**Comparison**
Input Sample	DNA	DNA	Same

Non-Clinical Performance Data 21 CFR 807.92(b)(1)

Non-clinical performance of the instrument was evaluated in a reproducibility study using a representative fragment analysis assay. The reproducibility study was performed across multiple sites, using different instruments, multiple operators, and across several days. The pre-established acceptance criteria were met.

Clinical Performance Data 21 CFR 807.92(b)(2)

Clinical performance studies were conducted across 3 US clinical laboratory sites, with multiple instruments using a representative fragment analysis assay and an appropriate method comparison assay. All pre-established performance criteria were met.

Conclusion 21 CFR 807.92(b)(3)

The proposed Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer with fragment analysis and sequencing, and the legally marketed Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzer and 3500 Dx Series Data Collection Software with sequencing use the same capillary electrophoresis technology and are the same instrument. The Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer did not require changes to the instrument hardware or firmware to expand the intended use to include fragment analysis. The change was made in the Applied Biosystems™ 3500 Dx Series Data Collection Software to enable the fragment analysis workflow in the Diagnostic mode.

Therefore, the Applied Biosystems™ 3500 Dx Genetic Analyzer and the Applied Biosystems™ 3500xL Dx Genetic Analyzer and the legally marketed device, the Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzer CS2 and 3500 Dx Series Software, are substantially equivalent based on the study data provided in this 510(k). In addition, the performance of the fragment analysis application has been demonstrated by Clinical and Non-Clinical performance studies using a representative assay.