

**SPECIAL 510(k): Device Modification
OIR Review Memorandum**

To: THE FILE

RE: DOCUMENT NUMBER K141220

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
The Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS Software
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**:
The SDS software will be changed to support an additional OS (Windows 7 in addition to Windows XP).

Update camera driver for Win 7/64 bit compatibility. The camera driver used in the current 7500 Fast Dx Real-time PCR Software v1.4 is not compatible with Windows 7 OS. The camera driver will be updated to make the software compatible with Windows 7 OS.

An audit and e-Signature report print preview & print defect will be corrected. The current instrument software does not allow the user to preview and print the Audit and e-Signature reports. This anomaly will be fixed to allow the user to preview and print the Audit and e-Signature reports

The current version of the SDS Software does not allow the user to open a file from the network drive or print a file to a network printer when it's running on a computer with the Window 7 OS. This function will be implemented to allow the user to open a file from a network drive and print to a network printer once the user logs in with their user name and password credentials.

A minor cosmetic change will be implemented by removing the "AB" button and "myScience" option from the software. These functions are no longer supported.
4. The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
5. **Comparison Information** (similarities and differences):

	New Device: Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software (K141220)	Predicate Device: Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software version 1.4 (K082562)
Intended Use	Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument with the SDS Software is a real-time nucleic acid amplification and five color fluorescence detection	Applied Biosystems® 7500 Fast Dx Real-Time PCR instrument with the SDS Software version 1.4 is a real-time nucleic acid amplification and detection system

	New Device: Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software (K141220)	Predicate Device: Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument with SDS Software version 1.4 (K082562)
	system for use with FDA cleared or approved tests on human-derived specimens. The 7500 Fast Dx Real-Time PCR instrument and SDS Software are intended for use in combination with in vitro diagnostic tests labeled for use on this instrument. The 7500 Fast Dx instrument is intended for use by laboratory professionals trained in laboratory techniques, procedures, and on use of the system.	that measures nucleic acid signals from reverse transcribed RNA and converts them to comparative quantitative readouts using fluorescent detection of dual-labeled hydrolysis probes. The 7500 Fast Dx instrument is to be used only by technologists trained in laboratory techniques, procedures, and on use of the analyzer.
Fundamental Technology/Detection	Real-time PCR	Same
Instrument Computer Operating System	Microsoft Windows 7	Microsoft Windows XP
Degree of Automation	Requires manual transfer of amplification mixture to amplification/detection instrument. Automated control of amplification, detection and data analysis	Same
Primary Operational Amplification and Detection Components	Integrated thermal cycler and microvolume fluorimeter for walk away PCR amplification and detection	Same
Amplification Reaction Volume	10-30 uL in 96-well Fast PCR plates	Same

6. A **Design Control Activities Summary** which includes:

- a) Software architecture document describing the software design structure and programming environment.
- b) Software lifecycle management plan contains requirements for the software development lifecycle of the product. It defines the approach for software development as a subset of Life Technologies' Product Commercialization Process (PCP). It also defines the approach to software maintenance through product decommissioning and disposal.
- c) Impact assessment report assessing the impact and user safety risk for 7500 Fast Dx Real-Time PCR Instrument software change to support new computer models with Windows 7 Professional 32/64 bit Operating System Service Pack 1.
- d) Sustaining project master plan describes the software development plan and test plan.

- e) Software verification test report describes the verification results of the 7500 Fast Dx SDS Software v1.4.1 in accordance to the Sustaining Project Master Plan.
- f) Revision level history.
- g) Software configuration management plan provides the guidance for the control of evolving software systems, including creation of a Software Configuration Management Plan (SCMP). It controls versioning and configuration management of software products. It defines an approach for software configuration management and version control system use as a subset of Software Development Lifecycle Procedure.
- h) Service and support plan along with a software release for deployment guideline.
- i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.
- j) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

7. A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use Enclosure.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.