



July 02, 2025

Life Technologies Corporation
Ángel Casanova-Torres, Ph.D., CMDA, RAC
Manager, Regulatory Affairs
7305 Executive Way
Frederick, MD 21704

Re: P240040

Trade/Device Name: Oncomine Dx™ Express Test

Product Code: PQP

Filed: November 12, 2024

Amended: November 18, 2024, November 27, 2024, April 17, 2025, July 01, 2025

Dear Dr. Ángel Casanova-Torres:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Oncomine Dx Express Test. This device is indicated for:

The Oncomine Dx™ Express Test is a qualitative *in vitro* diagnostic test that uses targeted next-generation sequencing (NGS) technology to detect substitutions, insertions, and deletions in 42 genes from DNA, copy number variants (CNVs) in 10 genes from DNA, and fusions or splice variants in 18 genes from RNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor samples, using the Genexus Dx™ Integrated Sequencer.

The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapy listed in Table 1 in accordance with the approved therapeutic product labeling.

Table 1. Companion Diagnostic Indications

Tissue Type	Gene	Variant	Targeted Therapy
Non-small cell lung cancer (NSCLC)	<i>EGFR</i>	<i>EGFR</i> exon 20 insertions	ZEGFROVY™ (sunvozertinib)

Additionally, the test is intended to provide tumor mutation profiling information to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasms. Genomic findings other than those listed in Table 1 are not prescriptive or conclusive for labeled use of any specific therapeutic product.

Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 4 months of shelf life for the assay reagents at the recommended storage conditions. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and must include the information required by 21 CFR 814.84. The Annual Report should also include any changes implemented through an approved Predetermined Change Control Plan (PCCP). We recommend that such changes implemented through an approved PCCP are included in a separate section in the Annual Report.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have agreed to provide the following non-clinical information in a report, which may be followed by a PMA supplement where applicable.

1. Life Technologies Corporation must provide data to support the use of core needle biopsy (CNB) and fine needle aspirate (FNA) samples as acceptable sample types with ODxET for the tumor profiling indication. The study results must be adequate to confirm the safety and effectiveness of the ODxET.
 - a. Life Technologies Corporation must provide data from a well-designed study to demonstrate the precision for detecting tumor profiling variants, such as single nucleotide variants (SNVs),

insertions, deletions, copy number variants (CNVs), and fusions, targeted by ODxET, using an adequate number of CNB and FNA samples representing multiple tumor types. The data from this study must be adequate to support the precision of ODxET for detection of tumor profiling variants in CNB and FNA specimen types.

- b. Life Technologies Corporation must provide data from a well-designed specimen equivalency study to demonstrate comparable performance of ODxET in detecting tumor profiling variants by comparing results from a sufficient number of CNB and FNA specimens to those from matched resection (reference) samples. The samples used in this assessment should include tumor profiling variants representing each variant class across multiple tumor types. The study results must be sufficient to support the use of CNB and FNA specimens as acceptable sample types with ODxET for the tumor profiling indication.

The final study protocols for the above studies should be submitted within 1 month of the PMA approval date. The final study data, study conclusions and study reports, and labeling revisions should be submitted within 12 months of the PMA approval date.

2. Life Technologies Corporation must provide results and software validation documentation from regression testing on the configuration with restricted reporting of certain Level 3 tumor profiling SNVs with variant allele frequencies below 5% to prevent reporting of false positives. The study results must be sufficient to support reasonable assurance that masking Level 3 tumor profiling SNVs with VAFs below 5% does not adversely affect the reporting of all targeted variants and does not introduce new concerns regarding the safety or effectiveness of the device. The final study data, study conclusions and study reports, and labeling revisions should be submitted within 6 months of the PMA approval date.

Be advised that failure to comply with any post-approval requirement constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 21 CFR 814.46(a)(2).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system>.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. FDA's review of your PMA also included the review and approval of your Predetermined Change Control Plans (PCCPs), titled "ODxET ADF Aggregation Protocol (Version A00)", "Preapproved

Software Change (Version A00)”, and “ODxET Tumor Profiling Variant Recategorization Protocol (Version A00)”. Under section 515C(a)(1) of the Act, a supplemental application is not required for a change to a device approved under section 515 of the Act, if such change is consistent with a PCCP approved pursuant to section 515C(a)(2) of the Act. Under 21 CFR 814.39(a), a PMA supplement is generally required before making a change affecting the safety or effectiveness of the device for which there is an approved PMA. Accordingly, if deviations from the PCCP result in a change in the device that could affect the safety or effectiveness of the device, then a PMA supplement would generally be required consistent with section 515C(a)(1) of the Act and 21 CFR 814.39(a). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1) and 502(o) of the Act, respectively. Additional information about changes that may require a PMA supplement are provided in the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" <https://www.fda.gov/media/81431/download>.

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR Part 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems> and on combination product post-marketing safety reporting is available at <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>.

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR Part 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found at <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals>. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Meerie Sheen, Ph.D. at 301-837-7442 or Meerie.Sheen@fda.hhs.gov.

Sincerely,

Soma Ghosh, Ph.D.
Acting Director
Division of Molecular Genetics and
Pathology
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health