



May 27, 2026

Foundation Medicine, Inc.
Abigail Ekeigwe
Manager, Regulatory Affairs
400 Summer Street
Boston, MA 02210

Re: P170019/S060
Trade/Device Name: FoundationOne® CDx
Product Code: PQP
Filed: September 20, 2024
Amended: February 4, 2025, April 1, 2025, April 22, 2026, May 14, 2026

Dear Abigail Ekeigwe:

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) supplement for the FoundationOne CDx to include a companion diagnostic (CDx) indication for the detection of HRR gene alterations (*ATM*, *ATR*, *BRCA1*, *BRCA2*, *CDK12*, *CHEK2*, *FANCA*, *MLH1*, *MRE11A*, *NBN*, *PALB2*, *RAD51C*) in patients with metastatic castrate-resistant prostate cancer (mCRPC) who may benefit from treatment with TALZENNA® (talazoparib) in combination with XTANDI® (enzalutamide). This device is indicated for the following:

FoundationOne®CDx (F1CDx) is a qualitative next generation sequencing based in vitro diagnostic test that uses targeted high throughput hybridization-based capture technology for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling. Additionally, F1CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for 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.

Table 1. Companion diagnostic indications

Tumor Type	Biomarker(s) Detected	Therapy
Breast cancer	<i>AKT1</i> E17K; <i>PIK3CA</i> R88Q, N345K, C420R, E542K, E545A, E545D, E545Q, E545K, E545G, Q546E, Q546K, Q546R, Q546P, M1043V, M1043I, H1047Y, H1047R, H1047L, and G1049R; and <i>PTEN</i> alterations	TRUQAP™ (capivasertib) in combination with FASLODEX® (fulvestrant)
	<i>ERBB2</i> (HER2) amplification	HERCEPTIN® (trastuzumab)
		KADCYLA® (ado-trastuzumab emtansine)
		PERJETA® (pertuzumab)
	<i>PIK3CA</i> mutations	ITOVEBI™ (inavolisib) in combination with palbociclib and fulvestrant
	<i>PIK3CA</i> mutations (C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y)	PIQRAY® (alpelisib)
Cholangiocarcinoma	<i>FGFR2</i> fusions and select rearrangements	PEMAZYRE® (pemigatinib)
Colorectal cancer	<i>KRAS/NRAS</i> wild-type (absence of mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146))	ERBITUX® (cetuximab)
		VECTIBIX® (panitumumab)
Melanoma	<i>BRAF</i> V600 mutation-positive	TECENTRIQ® (atezolizumab) in combination with COTELLIC® (cobimetinib) and ZELBORAF® (vemurafenib)

	<i>BRAF</i> V600E	BRAF Inhibitor Approved by FDA*
	<i>BRAF</i> V600E and V600K	BRAF/MEK Inhibitor Combinations Approved by FDA*
		MEKINIST® (trametinib)
Non-small cell lung cancer (NSCLC)	<i>ALK</i> rearrangements	ALECENSA® (alectinib)
		ALUNBRIG® (brigatinib)
		XALKORI® (crizotinib)
		ZYKADIA® (ceritinib)
	<i>BRAF</i> V600E	BRAFTOVI® (encorafenib) in combination with MEKTOVI® (binimetinib)
		TAFINLAR® (dabrafenib) in combination with MEKINIST® (trametinib)
	<i>EGFR</i> exon 19 deletions and <i>EGFR</i> exon 21 L858R alterations	EGFR Tyrosine Kinase Inhibitors (TKI) Approved by FDA*
	<i>EGFR</i> exon 20 T790M alterations	TAGRISSE® (osimertinib)
	<i>MET</i> single nucleotide variants (SNVs) and indels that lead to MET exon 14 skipping	TABRECTA® (capmatinib)
		TEPMETKO® (tepotinib)
	<i>ROS1</i> fusions	ROZLYTREK® (entrectinib)
Ovarian cancer	<i>BRCA1</i> , <i>BRCA2</i> alterations	LYNPARZA® (olaparib)
Pediatric low-grade glioma	<i>BRAF</i> V600 mutation-positive and <i>BRAF</i> fusions	OJEMDA™ (tovorafenib)
Prostate cancer	<i>BRCA1</i> , <i>BRCA2</i> alterations	AKEEGA® (niraparib + abiraterone acetate)

		LYNPARZA® (olaparib) in combination with abiraterone
	Homologous Recombination Repair (HRR) gene (<i>BRCA1, BRCA2, ATM, ATR, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, RAD51C</i>) alterations	TALZENNA® (talazoparib) in combination with XTANDI® (enzalutamide)
	Homologous Recombination Repair (HRR) gene (<i>BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D and RAD54L</i>) alterations	LYNPARZA® (olaparib)
Solid tumors	MSI-High	KEYTRUDA® (pembrolizumab)
	<i>NTRK1/2/3</i> fusions	ROZLYTREK® (entrectinib)
		VITRAKVI® (larotrectinib)
	<i>RET</i> fusions	RETEVMO® (selpercatinib)
	TMB $\geq$ 10 mutations per megabase	KEYTRUDA® (pembrolizumab)

*For the most current information about the therapeutic products in this group, go to:
<https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnosticdevices-in-vitro-and-imaging-tools>

Based upon the information submitted, the PMA supplement 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). 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.

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

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.

FMI will provide the following information in a post-approval report within 6 months of approval of this PMA supplement:

1. FMI will provide evidence, acceptable to FDA, that performance expectations with the currently deployed Genomics Platform Analysis Pipeline (AP), including the version at the time of the submission of your sPMA (v3.37.0), are representative of the performance in the clinical and analytical validation studies in P170019/S060. Such evidence may include regression testing using the clinical and analytical datasets to perform in silico reanalysis of the results obtained in the clinical and analytical validation studies in this supplement and confirmation that there is little or no deviation in the quality metrics for each of the samples to support the accuracy and precision of F1CDx remains the same.

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. 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 Beatriz Sanchez-Solana at 301-796-1629 or Beatriz.Sanchez-Solana@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