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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. **Submission Type:** Traditional

2. **Date Prepared:** May 17, 2024

3. **Submitter Information**

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4. Device Information

Product Code	Device Classification Name	Device Name	Submission Type/Number	Regulation Number	Class	Panel
QUK	Human Leukocyte Antigen (Hla) Typing Companion Diagnostic Test	SeCore™ CDx HLA Sequencing System	Traditional BK241074	866.5960	II	Immunology

5. Predicate Device:

Product Code	Device Classification Name	Device Name	Submission Type/Number	Regulation Number	Class	Panel
QUK	Human Leukocyte Antigen (Hla) Typing Companion Diagnostic Test	SeCore™ CDx HLA Sequencing System	Direct De Novo/ BR220737	866.5960	II	Immunology

6. Device Description

The SeCore CDx HLA Sequencing System uses a sequence-based typing (SBT) method to detect HLA-A alleles in genomic DNA purified from whole blood specimens. SeCore CDx HLA Sequencing Kits directly identify the DNA sequence of target HLA genes. Polymerase chain reaction (PCR) is used with SeCore primers to perform locus-specific DNA amplification. Sanger sequencing is then used to determine the nucleotide sequence of the amplified product. Resulting data files are analyzed with uTYPE CDx HLA Sequence Analysis Software, which compares sample sequences to reference sequences in the IPD-IMGT/HLA database for HLA allele assignment.

7. Intended Use and Indications for Use Statement

The SeCore CDx HLA Sequencing System is intended for the detection of human leukocyte antigen A-locus (HLA-A) alleles using genomic DNA isolated from whole blood samples. The device is intended to be used as a companion diagnostic (CDx) to aid in the selection of patients who may benefit from treatment or are likely to be at increased risk for serious

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adverse reactions because of treatment with therapies listed in the table below when used in accordance with approved therapeutic labeling.

Table 1: Proposed Indications for Use

Indication(s)	HLA Target Allele(s)	Therapy
Unresectable or Metastatic Uveal Melanoma	Eligible allele: HLA-A*02:01	KIMMTRAK® (tebentafusp-tebn)
Unresectable or Metastatic Synovial Sarcoma in Patients who have Received Prior Chemotherapy	Eligible alleles: HLA-A*02:01, HLA-A*02:02, HLA-A*02:03 or HLA-A*02:06 and their P-group alleles Exclusion alleles: HLA-A*02:05 and its P-group alleles	TECELRA® (afamitresgene autoleucel)

8. Nonclinical Studies

The SeCore CDx HLA Sequencing System has well established analytical performance characteristics from analytical studies conducted for 510(k)-clearance (refer to BK110038).

- Accuracy
- Precision, Reproducibility
- Stability
- Shipping/Transportation
- Detection Limit
- Sample Preparation
- Assay Cut-off
- Interference Testing

Two additional studies have been completed to support the SeCore CDx HLA Sequencing System for use as a companion diagnostic to ensure that the device is accurate within the target population and can effectively discriminate the required target allele(s).

- Detection of HLA-A*02:01 (KIMMTRAK®)
- Detection of HLA-A*02:01, HLA-A*02:02, HLA-A*02:03 or HLA-A*02:06 and their P-group alleles, excluding HLA-A*02:05 and its P-group alleles (TECELRA®)

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All test results demonstrated that subject device meets the requirements of its pre-defined acceptance criteria and intended use.

9. Clinical Testing

Samples from three testing sites (N=299) were tested to evaluate the equivalence between the SeCore Sequencing System and a predicate device (SSP UniTray with UniMatch Plus interpretation software). Test results demonstrated that subject device meets the requirements of its pre-defined acceptance criteria.

Additional companion diagnostic clinical trial studies were conducted using the SeCore CDx HLA Sequencing System for detection of human leukocyte antigen A-locus (HLA-A) alleles to aid in the selection of patients who may benefit from treatment with associated therapies. (Refer to Study Trials, IMCgp100-202 and ADP-0044-002)

10. Substantial Equivalence Determination

The device that is subject of the premarket notification submission has the same technological characteristics as the predicate device, the De Novo granted device previously cleared by FDA on November 28, 2022 (see BR220737).

A summary of the technological characteristics is as follows:

Table 5: Comparison with Proposed Predicate Device

	Predicate Device (BR220737)	**New Device (BK241074)**
Device Name	SeCore™ CDx HLA Sequencing System	Same
Submission Number	BR220737	Pending
Regulation Number	21 CFR 866.5960	Same
Regulation Name	Human leukocyte antigen typing companion diagnostic test	Same

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<table>
<tr><th></th><th>Predicate Device

(BR220737)</th><th>New Device

(BK241074)</th></tr>
<tr><td>Classification</td><td>Class II</td><td>Same</td></tr>
<tr><td>Product Code</td><td>QUK</td><td>Same</td></tr>
<tr><td>Intended Use</td><td>The SeCore CDx HLA Sequencing System is intended for the detection of human leukocyte antigen A-locus (HLA-A) alleles using genomic DNA isolated from whole blood samples. The device is intended to be used as a companion diagnostic (CDx) to aid in the selection of HLA-A*02:01 positive patients with unresectable or metastatic uveal melanoma who may benefit from treatment with KIMMTRAK® (tebentafusp-tebn) when used in accordance with approved therapeutic labeling.</td><td>The SeCore CDx HLA Sequencing System is intended for the detection of human leukocyte antigen A-locus (HLA-A) alleles using genomic DNA isolated from whole blood samples. The device is intended to be used as a companion diagnostic (CDx) to aid in the selection of patients who may benefit from treatment or are likely to be at increased risk for serious adverse reactions because of treatment with therapies listed in the table below when used in accordance with approved therapeutic labeling:
<table>
<tr><th>Indication(s)</th><th>HLA Target Allele(s)</th><th>Therapy</th></tr>
<tr><td>Unresectable or metastatic Uveal Melanoma</td><td>Eligible allele: HLA-A*02:01</td><td>KIMMTRAK® (tebentafusp-tebn)</td></tr>
<tr><td>Unresectable or Metastatic Synovial Sarcoma in Patients who have Received Prior Chemotherapy</td><td>Eligible alleles: HLA-A*02:01, HLA-A*02:02, HLA-A*02:03 or HLA-A*02:06 and their P-group alleles

Exclusion alleles: HLA-A*02:05 and its P-group alleles</td><td>TECELRA® (afamitresgene autoleucel)</td></tr>
</table></td></tr>
<tr><td>Indications for Use</td><td>For use in the Uveal Melanoma patient population.</td><td>For use in the unresectable or metastatic uveal melanoma and the unresectable or metastatic synovial sarcoma patient populations.</td></tr>
<tr><td>Assay Method</td><td>Sequence Based Typing</td><td>Same</td></tr>
<tr><td>Reactive Ingredient</td><td>Genomic DNA</td><td>Same</td></tr>
</table>

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	Predicate Device **(BR220737)**	**New Device** **(BK241074)**
Specimen Type(s)	Whole Blood	Same
Sample Type(s)	Purified DNA	Same
Detection Reagents	Fluorescent emission detection from BigDye™ Terminators	Same
Software Technology	Uses personal computer. Operates with a Windows 10 operating system	Same
Software Main Components	uTYPE CDx HLA Sequence Analysis Software	Same
Instrumentation	DNA Amplification: Veriti™ Dx 96-Well Thermal Cycler Model 9912 with 0.2–mL sample wells (Class I Device) Capillary electrophoresis: Applied Biosystems 3500 Dx /3500 xL Dx Genetic Analyzer CS2 (Class 2 Device, 510(k)-cleared BK110039)	Same

11. Conclusion

Analysis of the non-clinical, clinical, and safety and performance data concludes that the subject device SeCore CDx HLA Sequencing System is equivalent to the predicate device.