SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** K163347

This 510(k) submission contains information/data on modifications made to the Luminex' own Class II devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

   xTAG® Cystic Fibrosis (CFTR) 39 kit v2

   510(k) number: K083846

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):**.

   New software threshold values for 2183/2184 variants. The increased thresholds modify the probability of no-call/incorrect call.

   The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

Similarities between New Device and Predicate

Item	Modified Device	Predicate Device xTAG® Cystic Fibrosis 39
Intended Use	The xTAG® Cystic Fibrosis 39 kit v2 is a device used to simultaneously detect and identify a panel of mutations and variants in the Cystic Fibrosis transmembrane conductance regulator (CFTR) gene in human blood specimens. The panel includes mutations and variants currently recommended by the American College of Medical Genetics and American College of Obstetricians and Gynecologists (ACMG/ACOG), plus some of the world's most common and North American-prevalent mutations.	Same
Indications for Use	For carrier testing in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children.	Same
Contra-Indications	The kit is not indicated for use in fetal diagnostic or pre- implantation testing. This kit is also not indicated for stand- alone diagnostic purposes.	Same
Specimen Type	Peripheral human whole blood	Same
Methodology	Multiplex PCR followed by multiplex allele specific primer extension for genotyping, hybridized to multiplex fluorescent microparticles, detected by flow cytometry	Same

Software	TDAS CFTR contains 1 template to detect a panel of 3 mutations and 4 variants. Software has a masking function where user can choose to display results for either the ACMG/ACOG 23 mutations or for the full panel of mutations.	Same
Number of alleles detected	39 mutations and 4 variants in the CFTR gene (Includes 23 ACMG/ACOG recommended mutations)	Same
Instrument	Luminex 100/200	Same
Instrument Software	IS and xPONENT	Same

Differences between New Device and Predicate

Item	Modified Device	Predicate Device xTAG® Cystic Fibrosis 60 kit v2 (K083345)
Allelic ratio threshold for 2183/2184 tri-allelic variation (Full Panel)	Allelic ratio (AR) threshold for 2184delA mut allele set to 0.35 (LOW_HET_MUT2 threshold in TDAS CFTR). Process control threshold (PCT) for Presence of the 2184delA mut allele set to 0.40.	Allelic ratio (AR) threshold for 2184delA mut allele set to 0.20 (LOW_HET_MUT2 threshold in TDAS CFTR). Process control threshold (PCT) for Presence of the 2184delA mut allele set to 0.25.
Allelic ratio threshold for 2183/2184 bi-allelic variation (ACMG Panel)	Lower bound HET mutant AR threshold set to 0.35 (LOW_HET_MUT threshold in TDAS CFTR). PCT of the lower bound HET mutant AR set to 0.40	Lower bound HET mutant AR threshold set to 0.31 (LOW_HET_MUT threshold in TDAS CFTR). PCT of the lower bound HET mutant AR set to 0.36.

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

   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied. These

included (1) Report on the Process of Establishing Threshold Values for the 2183/2184 Variation of the xTAG® Cystic Fibrosis (CFTR) 39 kit v2; (2) Accuracy of mutation 2184delA with new thresholds in xTAG® Cystic Fibrosis (CFTR) 39 kit v2

6. 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.