SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION SUMMARY

510(k) Number: K191160

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

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1. The name and 510(k) number of the applicant's previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

   Trade Name: xTAG Gastrointestinal Pathogen Panel (GPP)
   510(k) Number: K183030

2. Applicant'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).

   Applicant states in the submission that the intended use of the modified device has not changed from its predicate. The intended use in the labeling is the same.

3. Description of the device **MODIFICATION(S):**

   This change was for the addition of the validated extraction platform, BioMerieux EMAG for use with the xTAG GPP device. The xTAG GPP device was cleared under K140377 for use with the BioMerieux NucliSENS easyMAG extraction platform. The purpose of the change is to allow customers to continue to use xTAG GPP after easyMAG is discontinued.

   The unmodified and modified devices are identical in assay formulation. The only changes are to the extraction platform as described above.

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

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

Similarities		
	Modified Device	**Predicate Device**
Features	xTAG Gastrointestinal Pathogen Panel (GPP) (K191160)	xTAG Gastrointestinal Pathogen Panel (GPP) (K183030)
Intended Use	Same as predicate device	The xTAG Gastrointestinal Pathogen Panel (GPP) is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and identification of multiple viral, bacterial, and parasitic nucleic acids in human stool specimens or human stool in Cary Blair media from individuals with signs and symptoms of infectious colitis or gastroenteritis. The following pathogen types, subtypes and toxin genes are identified using the xTAG GPP: Viruses • Adenovirus 40/41 • Norovirus GI/GII • Rotavirus A Bacteria • *Campylobacter* (*C. jejuni, C. coli* and *C. lari* only) • *Clostridium difficile* (*C. difficile*) toxin A/B • *Escherichia coli* (*E. coli*) O157 • Enterotoxigenic *Escherichia coli* (ETEC) LT/ST • *Salmonella* • Shiga-like Toxin producing *E. coli* (STEC) stx 1/stx 2 • *Shigella* (*S. boydii, S. sonnei, S. flexneri* and *S. dysenteriae*) • *Vibrio cholerae* (*V. cholerae*) Parasites • *Cryptosporidium* (*C. parvum* and *C. hominis* only) • *Entamoeba histolytica* (*E. histolytica*) • *Giardia* (*G. lamblia* only - also known as *G. intestinalis* and *G. duodenalis*) The detection and identification of specific gastrointestinal microbial nucleic acid from individuals exhibiting signs and symptoms of gastrointestinal infection aids in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation,

Similarities		
	Modified Device	**Predicate Device**
		laboratory findings and epidemiological information. A gastrointestinal microorganism multiplex nucleic acid-based assay also aids in the detection and identification of acute gastroenteritis in the context of outbreaks. xTAG GPP positive results are presumptive and must be confirmed by FDA-cleared tests or other acceptable reference methods. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Confirmed positive results do not rule out co-infection with other organisms that are not detected by this test, and may not be the sole or definitive cause of patient illness. Negative xTAG Gastrointestinal Pathogen Panel results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease. xTAG GPP is not intended to monitor or guide treatment for *C. difficile* infections. The xTAG GPP is indicated for use with the Luminex 100/200 and MAGPIX instruments with xPONENT software.
Sample Type	Same as predicate device	Human stool specimens and human stool in Cary-Blair media
Test Principle and Amplification	Same as predicate device	Multiplex end point RT-PCR
Test Format	Same as predicate device	Multiplex MAGPLEX bead-based universal array
Detection Method	Same as predicate device	Fluorescence based
Quality Control	Same as predicate device	Internal Control (MS2), rotating analyte controls and negative control (RNAse-free water)
Assay Result	Same as predicate device	Qualitative
Instrument	Same as predicate device	Luminex 100/200

Similarities		
	Modified Device	**Predicate Device**
Software	Same as predicate device	xPONENT Software

Differences		
	Modified Device	**Predicate Device**
Features	xTAG Gastrointestinal Pathogen Panel (GPP) (K191160)	xTAG Gastrointestinal Pathogen Panel (GPP) (K18030)
Extraction Method	Biomérieux NucliSENS easyMAG and EMAG	Biomérieux NucliSENS easyMAG

6. **Design Control Activities Summary**:

A risk assessment of the modified device was conducted based on the ISO 14971 risk management standard for medical devices and conducted in accordance with the established Risk Management Operating Procedure. The risk analysis report for the xTAG GPP and the software was performed as a system.

This hazard and risk analysis is based on critical thinking about the device design and the impact of any failure of sub-system components. The assessment included a summary of the fault conditions, potential hazards, current protections and additional risk mitigations (if any), as well as a qualitative assessment of the risk associated with each hazard. Items such as signal detection and analysis, data storage, system communications, cyber-security in relation to incorrect patient reports, LIS integration, instrument failures, operator safety, environmental conditions and influences, and effectiveness of recovery procedures, including disaster recovery, have been considered. This hazard & risk analysis aims to include all foreseeable hazards including those resulting from intentional or inadvertent misuse of the device. Risk was evaluated with respect to the end-user and the patient.

No new hazards or failure modes were identified with the use of EMAG extraction system with xTAG GPP.

To validate the modified device the following analytical and clinical studies were performed:

- **Dilution Study:** A validation study was performed to validate the equivalence of the BioMerieux eMAG automated nucleic acid purification system to the BioMerieux's previous generation system, the easyMAG on the xTAG Gastrointestinal Pathogen Panel (GPP) assay performed on the Luminex 200 system. The acceptance criteria for this study stated that the EMAG will be considered equivalent with the easyMAG system if; the last set of dilution replicates with 100% positivity for the EMAG is +/- 3x (one dilution level) the last set of dilution replicates with 100% positivity on the easyMAG.

  Results of the dilution study met the acceptance criteria and demonstrates that equivalent sensitivity was achieved between the eMAG and easyMAG for each of the six targets evaluated.

- **Method Comparison:** A retrospective clinical study was performed to validate the equivalents of the BioMerieux eMAG automated nucleic acid purification system to the BioMerieux's previous generation system, the easyMAG on the xTAG Gastrointestinal Pathogen Panel (GPP) assay performed on the Luminex 200 system. 231 retrospectively collected clinical samples (92 Cary-Blair stools and 139 raw stools) were extracted in parallel on both instrument and run on the xTAG GPP assay. Whenever possible the easyMAG and eMAG extracts were run in parallel on the same plate.

  The percent call agreement for each of the xTAG GPP targets ranged from 98.5% to 100%, meeting the study acceptance criteria of ≥ 95%.

The firm provided a summary of the results from these verification and validation studies. The results demonstrated that requirements were met and there was no negative impact to assay performance.

7. **Truthful and Accurate Statement**, a **510(k) Summary or Statement** 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 applicant'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 applicant 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.