SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE RE: K153223

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

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

   K132238 – ProParaFlu®+ Assay, Hologic, Inc.

   K091053 – ProParaFlu®+ Assay, Prodesse, Inc.

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.

3. A description of the device **MODIFICATION**, including a statement that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   Changes to the labeling include adding "Rx only" under the IVD symbol on the first page of the Instructions for Use and updating the Limitations section of the Instructions for Use regarding limited reactivity with the 2014 CAP sample ID2-08 and the 2015 CAP sample ID2-02. The following limitation was included: "The ProParaflu+ assay has limited reactivity with the 2014 CAP sample ID2-08 and the 2015 CAP sample ID2-02. Sequencing analysis of the CAP samples revealed that the HPIV3 target sequences of the CAP samples match the sequence of HPIV3/Homo sapiens/PER/FLU8889/2007 strain in GenBank (GenBank Accession # KJ672604), and the limited reactivity is most likely due to a viral mutation in the probe binding region. Negative results may be obtained for samples containing this variant especially at low titers. If the ProParaflu+ assay does not indicate a positive result when an HPIV-3 infection is suspected, the specimen should be retested for HPIV-3 using an independent method (e.g. cell culture or molecular IVD)".

   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, and physical characteristics.

Similarities		
Element	**Modified Prodesse ProParaflu+ Assay**	**Current Prodesse ProParaflu+ Assay (K091053)**
Organisms Detected	Same	HPIV-1, HPIV-2, and HPIV-3
Analyte	Same	RNA
Technological Principles	Same	Multiplex nucleic acid amplification
Specimen Types	Same	Nasopharyngeal Swab

Similarities		
Element	**Modified Prodesse ProParaflu+ Assay**	**Current Prodesse ProParaflu+ Assay (K091053)**
User Complexity	Same	High
Sample Preparation Method	Same	Up front sample processing is required to extract nucleic acid
Instrumentation	Same	bioMérieux NucliSENS easyMAG or Roche MagNA Pure and Cepheid SmartCycler II Instrument
Time to result	Same	Approximately 4 hours
Controls	Same	Internal control in each sample. External control processed with each batch of samples

Differences		
Element	**Modified Prodesse ProParaflu+ Assay**	**Current Prodesse ProParaflu+ Assay (K091053)**
Limitations	Limited reactivity with the 2014 CAP sample ID2-08 and the 2015 CAP sample ID2-02	Did not include information regarding limited reactivity with the 2014 CAP sample ID2-08 and the 2015 CAP sample ID2-02

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

      The risks of potentially missing the variant strain of the HPIV-3 virus, HPIV3/Homo sapiens/PER/FLU8889/2007 when testing with the ProParaflu+ Assay were evaluated by reviewing the Failure Mode Effects Analysis (FMEA) that had been performed during product development to determine whether the Instructions for Use (IFU) update creates new risks or failure modes or affects the risk priority number (RPN) value.

   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

      No new risks were identified for testing HPIV3/Homo sapiens/PER/FLU8889/2007 with the ProParaflu+ Assay. All RPNs were in categories “As Low As Reasonably Possible” (ALARP) or “Low Risk Category” and therefore, no additional risk control activities were necessary. No additional concerns of safety and efficacy were identified.

No device modifications were made. The Limitations section of the ProParaflu+ Assay IFU was updated to include a statement of limited reactivity with select HPIV-3 strains as described in section 3 above. To monitor for additional mutations over time, a monthly query will be performed against GenBank to retrieve all sequences for HPIV that encompass the target region and generate alignments against the sequences in production designs.

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.