

**SPECIAL 510(k): Device Modification
OIR Decision Summary**

To: Biofire Diagnostics LLC

RE: K160068

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

Trade Name: FilmArray Respiratory Panel (RP) for use with Multi-Instrument FilmArray System (2.0)
510(k) Number: K143080

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device, called "FilmArray® Respiratory Panel for use with FilmArray Torch", as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, and package labeling.

Submitter states in the labeling, 510(k) Summary, and in the submission that the intended use of the modified device has not changed from its predicate.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, assay instruction and instrument operations manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

The modifications of the FilmArrayTorch comprise a reconfigured instrument to increase throughput and reduce workspace. Changes include:

- a reconfigured base instrument tower with optional, stacked, individual, instrument modules,
- workflow altered for a manual read of the assay pouch bar-code by operator instead of automatic read within instrument,
- automatic side-loading and ejection of the assay pouch instead of manual top-loading,
- printer optional instead of printer included,
- computer and touch screen integrated into the base tower instead of a separate computer,
- operation with kiosk-style software,
- labeling appended with additional operation procedure and with statements describing the validation studies; these studies included an intra-laboratory precision study for the modified device.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and software is shown in the table below.

Element	Modified Device: FilmArray Respiratory Panel for use with FilmArray Torch (K160068)	Predicate: FilmArray Respiratory Panel for use with the Multi-instrument FilmArray System (FilmArray 2.0) (K143080)
Organisms Detected	Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Respiratory Syncytial Virus, Human Metapneumovirus, Adenovirus, Parainfluenza 1, Parainfluenza 2, Parainfluenza virus 3, Parainfluenza 4, Human Rhinovirus/Enterovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, <i>Mycoplasma pneumoniae</i> , <i>Chlamydomphila pneumoniae</i> , and <i>Bordetella pertussis</i> .	Same
Analyte	RNA/DNA	Same
Specimen Types	Nasopharyngeal swabs	Same
Technological Principles	Nested multiplex RT-PCR followed by high resolution melting analysis to confirm identity of amplified product.	Same
Instrumentation	Single instrument FilmArray system, FilmArray 2.0 system, or FilmArray Torch system	Single instrument FilmArray system or FilmArray 2.0 system
Instrument-Software Communication	Communication for multiple FilmArray Torch Modules travels via Ethernet cable/port.	Same (multiple instruments)
Time to result	About 1 hour	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data.	Same
Reagent Hydration and Sample Loading	Syringe-based loading procedure or FilmArray Injection Vial-based loading procedure	Same
Sample Preparation Method	Sample Processing is automated in the FilmArray RP pouch.	Same
Reagent Storage	Reagents are stored at room temperature.	Same
Controls	Two controls are included in each reagent pouch to monitor sample processing and both stages of PCR and melt analysis.	Same
User Complexity	Moderate/Low	Same

The indications for use provided below are identical for both devices.

FilmArray 2.0 (K143080) Indications for use (same as K160068):

The FilmArray Respiratory Panel (RP) is a multiplexed nucleic acid test intended for use with FilmArray systems for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections. The following organism types and subtypes are identified using the FilmArray RP: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, *Bordetella pertussis*, *Chlamydomphila pneumoniae*, and *Mycoplasma pneumoniae*. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and symptoms of a respiratory infection aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other management decisions. Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test or, lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen. Positive results do not rule out co- infection with other organisms: the agent(s) detected by the Film Array RP may not be the definite cause of disease. Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.

Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for *Bordetella pertussis*, Coronavirus 229E, Coronavirus OC43, Influenza A H1, Influenza A H3, Influenza A H1-2009, Influenza B, *Mycoplasma pneumoniae*, Parainfluenza Virus 1, Parainfluenza Virus 2, and Parainfluenza Virus 4 were established primarily with retrospective clinical specimens. Performance characteristics for *Chlamydomphila pneumoniae* were established primarily using contrived clinical specimens.

Due to the genetic similarity between Human Rhinovirus and Enterovirus, the FilmArray RP cannot reliably differentiate them. A positive FilmArray RP Rhinovirus/Enterovirus result should be followed-up using an alternate method (e.g., cell culture or sequence analysis).

The FilmArray RP assay for Coronavirus OC43 may cross-react with some isolates of Coronavirus HKU1. A dual positive result may be due to cross-reactivity or may indicate a co-infection.

Performance characteristics for Influenza A were established when Influenza A 2009 H1N1, A H1, and A H3 were the predominant Influenza A viruses in circulation. Performance of detecting Influenza A may vary if other Influenza A strains are circulating or a novel Influenza A virus emerges. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

5. A **Design Control Activities Summary** was present 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.

Risk analysis was performed to identify risks, their possible causes, and appropriate control mechanisms. Risk management of the FilmArray Torch Software and Firmware followed processes that are compliant with ISO 14971:2012, Medical devices – application of risk management to medical devices. After mitigation, all hazards associated with the FilmArray Torch Software have a Risk score of “No Risk”.

To validate the modified device, an intra-laboratory precision study was conducted. Results of precision testing on the FilmArray Torch systems indicate that all analytes in the device intended use (at 1x LoD based on FilmArray 2.0) were detected in at least 95% of the samples tested.

In addition to analyte detection, the precision of FilmArray RP T_m (melting temperature) results on FilmArray Torch was evaluated. The standard deviation in T_m for each assay on each of the 3 FilmArray Torch systems and overall (all systems/Modules) met the acceptance criteria of 0.5°C or less.

Method comparison studies with different types of samples were conducted for the modified device (FilmArray Torch) and its predicate device (FilmArray 2.0). These included a synthetic template method comparison study, a negative sample method comparison study, and a representative organism method comparison study. For all studies, the positive agreement was ≥95% and the negative agreement was 100%.

- c) Declaration of Conformity to Design Controls

A “Declaration of Conformity” statement was submitted for the Biofire Diagnostics, LLC manufacturing facility. It was signed by the Vice President, Regulated Products and Clinical Affairs, and the Director of Quality Assurance. The statements indicate that:

- i. “To the best of my knowledge, the verification activities for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.”
- ii. “The manufacturing facility, Biofire Diagnostics, LLC, is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.”

6. Conclusion

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 device.