



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Hologic, Inc.
Ron Domingo
Regulatory Affairs Manager
10210 Genetic Center Drive
San Diego, CA 92121

November 20, 2015

Re: K153219
Trade/Device Name: Prodesse® Proflu™ + Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OCC
Dated: November 3, 2015
Received: November 5, 2015

Dear Mr. Domingo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tamara V. Feldblyum -S for

Uwe Scherf, M.Sc., Ph.D.
Director
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Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153219

Device Name
Prodesse® ProFluTM+

Indications for Use (Describe)

The Prodesse® ProFluTM+ Assay is a multiplex Real-Time PCR (RT-PCR) in vitro diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to aid in the differential diagnosis of Influenza A, Influenza B and RSV viral infections in humans and is not intended to detect Influenza C.

Negative results do not preclude influenza or RSV virus infection and should not be used as the sole basis for treatment or other management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.

Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation (2006 – 2007 respiratory season). Performance characteristics for Influenza A were confirmed when Influenza A/H1, Influenza A/H3, and Influenza A/2009 H1N1 were the predominant Influenza A viruses in circulation (2008 and 2009). When other Influenza A viruses are emerging, performance characteristics may vary.

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 department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

Contact

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Name of Device

Trade Name:	Prodesse® ProFlu™+ Assay
Regulation Number:	21 CFR 866.3980
Classification Name:	Respiratory Virus Panel Multiplex Nucleic Acid Assay
Product Code:	OCC

Predicate Devices

K081030 – ProFlu™+ Assay, Hologic, Inc.
K132129 – ProFlu+ Assay, Gen-Probe Prodesse, Inc.

Intended Use

The Prodesse® ProFlu™+ Assay is a multiplex Real-Time PCR (RT-PCR) in vitro diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to aid in the differential diagnosis of Influenza A, Influenza B and RSV viral infections in humans and is not intended to detect Influenza C.

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Product Description

The ProFlu+ Assay enables detection and differentiation of Influenza A Virus, Influenza B Virus, Respiratory Syncytial Virus (RSV) (Types A and B), and Universal Internal Control nucleic acids. Nasopharyngeal swab specimens are collected from symptomatic patients using a polyester, rayon or nylon tipped swab and place into viral transport medium.

A Universal Internal Control (UIC) is added to each sample prior to nucleic acid isolation to monitor for inhibitors present in the specimens. The isolation and purification of the nucleic acids is performed using either a MagNA Pure LC Instrument (Roche) and the MagNA Pure Total Nucleic Acid Isolation Kit (Roche) or a NucliSENS® easyMAG™ System (bioMérieux) and the Automated Magnetic Extraction Reagents (bioMérieux).

The purified nucleic acids are added to Influenza A/Influenza B/RSV Mix along with enzymes included in the ProFlu+ Assay Kit. The Influenza A/Influenza B/RSV mix contains oligonucleotide primers and target-specific oligonucleotide probes. The primers are complementary to highly conserved regions of genetic sequences for these respiratory viruses. The probes are dual-labeled with a reporter dye and a quencher.

Reverse transcription of the RNA in the sample into complementary DNA (cDNA) and subsequent amplification of DNA is performed in a Cepheid SmartCycler® II instrument. In this process, the probe anneals specifically to the template followed by primer extension and amplification. The ProFlu+ Assay is based on Taqman chemistry, which utilizes the 5' – 3' exonuclease activity of the Taq polymerase to cleave the probe thus separating the reporter dye from the quencher. This generates an increase in fluorescent signal upon excitation from a light source. With each cycle, additional reporter dye molecules are cleaved from their respective probes, further increasing fluorescent signal. The amount of fluorescence at any given cycle is dependent on the amount of amplification products present at that time. Fluorescent intensity is monitored during each PCR cycle by the SmartCycler II instrument.

Substantial Equivalence

The Intended Use and Warnings and Precautions of the modified device as described in the labeling have not changed compared to the predicate device. The modifications detailed in the table below had not had any effect or caused any changes to the fundamental scientific technology of the device.

Similarities and Differences		
Element	Modified Prodesse ProFlu+ Assay	Current Prodesse ProFlu+ Assay (K132129)
Similarities		
Organisms Detected	Same	Influenza A virus, Influenza B virus, Respiratory Syncytial Virus
Analyte	Same	RNA
Technological Principles	Same	Multiplex nucleic acid amplification
Specimen Types	Same	Nasopharyngeal Swab
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		
Detection of new strain	Influenza A/H3N2 strain, A/New York/1/2015	Influenza A/H3N2 strain, A/New York/1/2015 was not listed in the Reactivity Table of the PI

Summary of Data for the Modified Device

A study was performed to test the reactivity of the ProFlu+ Assay to an emerging strain of Influenza A, A/New York/1/2015 (H3N2). Results show the Assay was able to detect the nucleic acids of the cultured virus at a concentration of 2×10^1 TCID₅₀/mL. The results are used to support the changes in the ProFlu+ Instructions for Use by including the additional reactivity information.