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Food and Drug Administration
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Clever Culture Systems AG
c/o Dr. Arthur Brandwood
Brandwood Biomedical
1 Chandos Street,
St. Leonards,
AU 2065 NSW

Re: DEN150059
APAS Compact
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 866.2190
Regulation Name: Automated image assessment system for microbial colonies on solid culture media
Regulatory Classification: Class II
Product Code: PPU
Dated: December 21, 2015
Received: December 24, 2015

Dear Dr. Brandwood:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the APAS Compact a prescription device. The indication(s) for use of the APAS Compact with Urine Analysis Module is:

The APAS Compact is an *in vitro* diagnostic system comprised of an instrument for automated imaging of agar culture plates and a software analysis module for the following use:

The APAS Compact, when using its urine analysis module, automates urine culture plate imaging and interpretation to detect the presence or absence of microbial growth on sheep blood and MacConkey agar culture plates that are inoculated with a 1 μ L sample volume. The APAS Compact, when using its urine analysis module, provides a semi-quantitative assessment of colony counts that are used as an aid in the diagnosis of urinary tract infection. All urine culture plates that are identified as positive for growth by the APAS Compact, when using its urine analysis module, must be reviewed by a trained microbiologist.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the APAS Compact, and substantially equivalent devices of this generic type, into class II under the generic name, “Automated image assessment system for microbial colonies on solid culture media.”

FDA identifies this generic type of device as: **Automated image assessment system for microbial colonies on solid culture media**

An automated image assessment system for microbial colonies on solid culture media is a system that is intended to assess the presence or absence of microbial colonies on solid microbiological culture medium, and to interpret their number, phenotypic and morphologic characteristics through analysis of two dimensional digital images as an aid in diagnosis of infectious disease.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On December 24, 2015, FDA received your *de novo* requesting classification of the APAS Compact into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the APAS Compact with Urine Analysis Module into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request , FDA has determined that the APAS Compact indicated for use as follows:

The APAS Compact is an *in vitro* diagnostic system comprised of an instrument for automated imaging of agar culture plates and a software analysis module for the following use:

The APAS Compact, when using its urine analysis module, automates urine culture plate imaging and interpretation to detect the presence or absence of microbial growth on sheep blood and MacConkey agar culture plates that are inoculated with a 1 μ L sample volume. The APAS Compact, when using its urine analysis module, provides a semi-quantitative assessment of colony counts that are used as an aid in the diagnosis of urinary tract infection. All urine culture plates that are identified as positive for growth by the APAS Compact, when using its urine analysis module, must be reviewed by a trained microbiologist.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II special controls identified later in this order, along with applicable general controls, including the design controls under 21 CFR part 820, provide reasonable assurance of the

safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Identified Mitigations
False positive results (i.e., incorrect designation of plates for “Review” or as “Positive”)	General controls and special controls: (1), (2), (3), (4), (5), (6), (7)
False negative results (i.e., failure to detect growth and incorrect designation of plates as “Negative”)	General controls and special controls: (1), (2), (3), (4), (5), (6), (7)

In combination with the general controls of the FD&C Act, the Automated image assessment system for microbial colonies on solid culture media is subject to the following special controls:

1. Pre-market notification submissions must include a detailed description of the device, including the technology employed, components and software modules, as well as a detailed explanation of the result algorithms and any expert rules that are used to assess colony characteristics and enumerate colonies from image capture through end result.
2. Pre-market notification submissions must include detailed documentation of the analytical studies performed to characterize device performance to support the intended use, as appropriate.
3. Pre-market notification submissions must include detailed documentation from clinical studies performed on a population that is consistent with the intended use population.
 - i. The clinical studies must establish the device performance based on comparison to results obtained by an acceptable reference method, as appropriate.
 - ii. The clinical study documentation must include the study protocol with a predefined statistical analysis plan and the final report documenting support for the Indications for Use and the results of the statistical analysis, as appropriate.
4. Pre-market notification submissions must include detailed documentation for device software, including but not limited to software applications and hardware based components that incorporate software, and any decision making thresholds used to generate results for the device. If a part of a Total Laboratory Automation System, the pre-market notification submission must include detailed documentation addressing the instrument and software system integration.

5. Pre-market notification submissions must include detailed documentation of appropriate instructions for use regarding the intended user's device quality control procedures for the instrument system and components, as appropriate.
6. The 21 CFR 809.10 compliant device labeling must include:
 - i. Detailed user instructions to mitigate the risk of failure to operate the instrument correctly.
 - ii. A detailed explanation of the interpretation of results and limitations regarding the need for review of culture plates by a qualified microbiologist, as appropriate.
 - iii. A summary of performance data obtained from the analytical studies used to support device performance, as appropriate.
 - iv. A summary of performance data obtained from clinical studies performed on a population that is consistent with the intended use population, as appropriate.
7. Under 21 CFR 820.30 compliant design control, device manufacturers must, as appropriate:
 - i. Conduct human factors/usability validation testing with the final version of the labeling and related materials to adequately mitigate the risk of failure to operate the instrument correctly.
 - ii. Document a device training program that will be offered to the end user to adequately mitigate the risk of failure to operate the instrument correctly.

In addition, this is a prescription device. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Automated image assessment system for microbial colonies on solid culture media they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Tobin Hellyer at 301-796-6154.

Sincerely,

for Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and
Radiological Health