July 3, 2023

Aardvark Medical, Inc.
Steven Bacich
CEO
204 Cardinal Drive, Suite 300
Denton, TX 94960 United States

Re: K221664
Trade/Device Name: CLEARinse CTS Specimen Collection and Transport System
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial Nucleic Acid Storage And Stabilization Device
Regulatory Class: Class II
Product Code: QBD
Dated: June 7, 2022
Received: June 8, 2022

Dear Steven Bacich:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221664

Device Name
CLEARinse CTS

Indications for Use *(Describe)*
CLEARinse CTS is intended to collect and transport clinical nasal wash aspirate specimens that may contain influenza A or influenza B virus, by health care professionals, from the collection site to a laboratory or testing site. CLEARinse CTS specimens are suitable for use with legally marketed lateral flow immunoassays and molecular assays. CLEARinse CTS is for professional in-vitro diagnostic use.

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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510(K) SUMMARY

Submitter's Name and Address:
Aardvark Medical Company.
204 Cardinal Drive, Suite 300
Denton, TX 94960 United States

Contact Name and Information:
Steven Bacich
650-218-5934
stevenbacich@gmail.com

Date prepared:
June 7, 2023

Device Information:

Trade/Proprietary Name:	CLEARinse™ CTS Specimen Collection and Transport System
Common or Usual Name:	Microbial Nucleic Acid Storage and Stabilization Device
Classification Name:	Microbial Nucleic Acid Storage and Stabilization Device
Classification Number:	Class II, 21 CFR 866.2950
Product Code:	QBD

Predicate Device:

510(k) Number	Device	Product Code
DEN170029	PrimeStore® MTM	QBD

Device Description:
CLEARinse CTS Specimen Collection and Transport System

CLEARinse CTS is intended to collect and transport clinical nasal wash aspirate specimens that may contain influenza A or influenza B virus, by health care professionals, from the collection site to a laboratory or testing site. CLEARinse CTS specimens are suitable for use with legally marketed lateral flow immunoassays and molecular assays. CLEARinse CTS is for professional in-vitro diagnostic use.

The product is an extension of the CLEARinse Pro device, a 510(k)-cleared (K082762) professional use medical device with indications for nasal lavage as well as mucus sample collection for subsequent testing. The CLEARinse Pro device has two main components: a pump-containing Handle and a disposable collection Wash Head. The CLEARinse Pro Handle and Instructions for Use are required for use of the CLEARinse CTS.

The CLEARinse CTS is comprised of two component assemblies: a revision to the 510(k)-cleared Wash Head and a Transport Container to protect the Wash Head and specimen during

transit. The CLEARinse CTS, used with the CLEARinse Pro Handle, will allow a nasal wash aspirate specimen to be collected by a medical professional, protected for transit, and ground shipped to a testing site. The user mounts the CLEARinse CTS Wash Head onto the CLEARinse Pro Handle and adds sterile saline as directed. The tip of the Wash Head is inserted into the patient's nostril and sterile saline is introduced. The irrigated saline and nasal secretions are then aspirated back into the Wash Head, collecting the specimen to be tested. The CLEARinse CTS Wash Head is removed from the Handle and placed into the Transport Container assembly (Container Cup, Filter Seal, Silicone Seal, and Container Lid) and then back into the CLEARinse CTS box for ground transportation of the specimen to a laboratory for testing.

The Wash Head is manufactured from inert, biocompatible plastics and is supplied as a sterile, single use device. The Transport Container is also manufactured from inert, biocompatible plastics and is a single use device but is not supplied sterile.

Indications for Use/Intended Use:
CLEARinse CTS is intended to collect and transport clinical nasal wash aspirate specimens that may contain influenza A or influenza B virus, by health care professionals, from the collection site to a laboratory or testing site. CLEARinse CTS specimens are suitable for use with legally marketed lateral flow immunoassays and molecular assays. CLEARinse CTS is for professional in-vitro diagnostic use.

Comparison of Technological Characteristics:

Device & Predicate Device(s):	Subject: K221664	Predicate: DEN170029
Device Trade Name	CLEARinse CTS: Specimen Collection and Transport System	PrimeStore MTM
General Device Characteristic Similarities		
Intended Use/Indications For Use	CLEARinse CTS is intended to collect and transport clinical nasal wash aspirate specimens that may contain influenza A or influenza B virus, by health care professionals, from the collection site to a laboratory or testing site. CLEARinse CTS	PrimeStore MTM is intended for the stabilization, transportation and inactivation of infectious unprocessed nasal washes suspected of containing Influenza a virus RNA. PrimeStore MTM is also intended for the stabilization,

	specimens are suitable for use with legally marketed lateral flow immunoassays and molecular assays. CLEARinse CTS is for professional in-vitro diagnostic use.	transportation and inactivation of infectious unprocessed sputum samples suspected of containing Mycobacterium tuberculosis DNA from human samples.
Material	Polypropylene	Same
General Device Characteristic Differences		
Specimen Type	Nasal Wash Aspirate suspected of containing influenza A or B viruses	Nasal wash suspected of containing Influenza A virus. Sputum samples suspected of containing MTB.
Transport Media Formulation	0.9% saline from nasal wash	Nucleic Acid Stabilization solution
Device Material Supplied	Wash Head and Transport Container	Molecular Transport Medium provided in cryogenic tube
Sterility	Sterile	Not sterile
Inactivation	No inactivation of viruses or bacteria	Inactivation of influenza A and MTB by Guanidine thiocyanate
Specimen Collection	Collection using the CLEARinse Pro Handle and Instructions for Use	Collection using standard clinical procedures

The Aardvark Medical Company CLEARinse CTS Device is substantially equivalent to the legally marketed predicate device. The CLEARinse CTS Device has the same intended use, similar indications for use, and similar technological characteristics for transporting nasal wash specimens to the laboratory as the predicate device. Performance data demonstrates that the CLEARinse CTS Device is as safe and effective.

Performance Data:

Detection Limit

Limit of Detection (LoD) testing was conducted to determine the lowest concentration of influenza A and influenza B that contains measurable nucleic acids or measurable antigens. Recovery of target analyte from the transport media, with a greater than 95% accuracy, was conducted by spiking pooled negative clinical nasal wash matrix (NWA and 0.9% saline solution) with various concentrations of influenza nucleic acid or antigen. The contrived samples were then placed into and removed from the Wash Head. The recovered samples are then placed into the workflow for the Cepheid® Xpert® Xpress SARS-CoV-2/Flu/RSV and Princeton BioMeditech Corporation (PBM) BioSign® Flu A+B assays. The results are compared to established LoD for the reference assays, found in their respective Package Inserts (PI).

A. PCR LoD Test Results:

Preliminary LoD testing was initially performed by spiking multiple concentrations of three different strains of influenza into NWA. The three viral concentrations used were 3X, 1X, and 0.5X of the established LoDs of similar influenza strains (Table 1) in the PI for the reference assay. The assay used was the EUA authorized, real-time reverse transcription polymerase chain reaction (PCR) Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV Cartridge using the GeneXpert® Xpress System. Positive and negative results were determined as explained in the PI for the device.

Table 1. Proposed test levels for Cepheid PCR testing for preliminary LoD study

Virus Type	Strain tested with CTS device	Reported LoD of Similar Strain*
Influenza A, H1N1	A/Netherlands/602/2009	4.0×10^{-3} $TCID_{50}$/mL for A/California/7/2009(H1N1)
Influenza A, H3N2	A/Indiana/10/2011	8.7×10^{-2} $TCID_{50}$/mL for A/Victoria/361/2011(H3N2)
Influenza B	B/Florida/07/2004	4.0×10^{-2} $TCID_{50}$/mL for B/Massachusetts/2/2012

*Note: strains used to determine analytical sensitivity (LoDs) for validation of the Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV Cartridge

For the Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV PCR test, LoD range-finding results indicated that the influenza A (FluA) samples contrived by the sponsor performed similarly to those used by Cepheid to establish the reported LoDs. For both FluA viruses, all three replicates were positive at 1X and 3X the reported LoD (Table 2). At 0.5X the reported LoD, each virus was negative for one or more replicates, indicating that the 1X level was truly near the LoD using the viral stocks listed in Table 1. For the influenza B (FluB), testing at 10-fold lower levels (0.05X – 0.3X) resulted in similar qualitative results: all three replicates positive at 0.1X and 0.3X, and only two of three replicates positive at 0.05X (Table 2).

Table 2. Preliminary PCR LoD estimation results with individual LoDs highlighted in grey.

Flu Type	Test Level	Qualitative Results	Mean Ct*

	Description	$TCID_{50}$/mL	# Positive	% Positive	
FluA H1N1	3X	1.2E-02	3 of 3	100%	34.9
	1X	4.0E-03	3 of 3	100%	36.8
	0.5X	2.0E-03	2 of 3	67%	37.4
FluA H3N2	3X	2.6E-01	3 of 3	100%	35.6
	1X	8.7E-02	3 of 3**	100%	36.9
	0.5X	4.3E-02	0 of 3	0%	N/A
FluB	0.3X	1.2E-02	3 of 3	100%	36.0
	0.1X	4.0E-03	3 of 3	100%	38.8
	0.05X	2.0E-03	2 of 3	67%	38.1

*Note: Mean Ct for FluA viruses are calculated based on the FluA1 analyte, which produced consistent Ct values.

**One replicate was positive on FluA1 and was negative on FluA2 and was considered below the LoD.

Confirmatory LoD testing was conducted with 20 replicates using contrived samples. The samples for the confirmatory testing were contrived using the sample procedure that was used for the preliminary study. The Ct values for the 20 replicates of the confirmatory tests for each of the three influenza strains are shown in Tables 3-5. Influenza A H1N1 had one Ct value out of acceptance range for analyte FluA1 resulting in 19 out of 20 results within the acceptance range of +/- 3 Ct of the mean. Both influenza A H3N2 and B had 20 out of 20 Ct values for either analyte FluA1 or FluB, respectively, within the acceptance range.

Table 3. PCR LoD confirmation results for influenza A H1N1 with out of acceptance range FluA1 Ct values highlighted in grey.

Concentration (1X LoD)	Replicate	FluA1 Result	FluA1 Ct	FluA2 Ct
4.00E-03	1	Positive	35.8	36.7
4.00E-03	2	Positive	35.2	36.4
4.00E-03	3	Positive	35.3	37
4.00E-03	4	Positive	38	41.1
4.00E-03	5	Positive	35.1	36.5
4.00E-03	6	Positive	36	37.8
4.00E-03	7	Positive	35.7	38.2
4.00E-03	8	Positive	35.9	40
4.00E-03	9	Positive	36.5	37.8
4.00E-03	10	Positive	35.6	37.2
4.00E-03	11	Positive	36.9	38.6

4.00E-03	12	Positive	35.4	36.8
4.00E-03	13	Positive	32.2	34.3
4.00E-03	14	Positive	35.2	36.1
4.00E-03	15	Positive	34.4	35.3
4.00E-03	16	Positive	36	38.6
4.00E-03	17	Positive	34.9	36.7
4.00E-03	18	Positive	36.3	37.8
4.00E-03	19	Positive	35.3	37.2
4.00E-03	20	Positive	35.5	37.3

Table 4. PCR LoD confirmation results for influenza A H3N2 with out of acceptance range FluA1 Ct values highlighted in grey.

Concentration (1X LoD)	Replicate	FluA1 Result	FluA1 Ct	FluA2 Ct
2.60E-01	1	Positive	37.1	ND
2.60E-01	2	Positive	36.1	40
2.60E-01	3	Positive	37.7	39
2.60E-01	4	Positive	35.1	37
2.60E-01	5	Positive	35.4	43
2.60E-01	6	Positive	34.3	37
2.60E-01	7	Positive	35.3	ND
2.60E-01	8	Positive	35.5	38
2.60E-01	9	Positive	35.3	39
2.60E-01	10	Positive	35	37
2.60E-01	11	Positive	35.2	39
2.60E-01	12	Positive	35.8	38
2.60E-01	13	NA*	NA*	NA*
2.60E-01	14	Positive	35.2	38
2.60E-01	15	Positive	35.6	38
2.60E-01	16	Positive	36	39
2.60E-01	17	Positive	35.3	39
2.60E-01	18	Positive	35.6	39
2.60E-01	19	Positive	35.5	38
2.60E-01	20	Positive	34.9	37
2.60E-01	21	Positive	35.5	41

*Note: Error. Probe check failed with the output of "NO RESULT – REPEAT TEST."

Table 5. PCR LoD confirmation results for influenza B with out of acceptance range FluB Ct values highlighted in grey.

Concentration (1X LoD)	Replicate	FluB Result	FluB Ct
4.00E-03	1	Positive	36.1

4.00E-03	2	Positive	36.1
4.00E-03	3	Positive	36.1
4.00E-03	4	Positive	36.3
4.00E-03	5	Positive	36.5
4.00E-03	6	Positive	36.7
4.00E-03	7	Positive	36.3
4.00E-03	8	Positive	36.2
4.00E-03	9	Positive	36.9
4.00E-03	10	Positive	36.2
4.00E-03	11	Positive	35.8
4.00E-03	12	Positive	35.9
4.00E-03	13	Positive	35.7
4.00E-03	14	NA*	NA*
4.00E-03	15	Positive	36.3
4.00E-03	16	Positive	36.6
4.00E-03	17	Positive	39.2
4.00E-03	18	Positive	36.4
4.00E-03	19	Positive	35.9
4.00E-03	20	Positive	37.1
4.00E-03	21	Positive	36.4

*Note: Error. Probe check failed with the output of "NO RESULT – REPEAT TEST."

In summary, the testing performed established that for PCR assays 4.0 $x10^{-3}$ $TCID_{50}$/mL is the LoD for both influenza A(H1N1) and B, and that 2.6 $x10^{-1}$ $TCID_{50}$/mL is the LoD for influenza A(H3N2).

B. LFA LoD Test Results:

Preliminary LoD testing was initially performed by spiking multiple concentrations of three different strains of influenza into NWA. The three viral concentrations used were 3X, 1X, and 0.5X of the established LoDs of similar influenza strains (Table 6) in the PI for the reference assay. The preliminary results indicated that additional antigen concentrations needed to be tested beyond the initially planned levels. The assay used was the PBM BioSign® Flu A+B lateral flow assay (LFA) (K182157). Positive and negative results were determined as explained in the PI for the device.

Table 6. Proposed test levels for PBM BioSign LFA testing for preliminary LoD study

Virus Type	Strain tested with CTS device	Reported LoD of Similar Strain*
Influenza A, H1N1	A/Netherlands/602/2009	1.1 x 10^2 $TCID_{50}$/mL for A/PR/8/34(H1N1)
Influenza A, H3N2	A/Indiana/10/2011	10 x 10^1 $TCID_{50}$/mL for A/Victoria/3/75(H3N2)

Influenza B	B/Florida/07/2004	2.0 x 10^1 $TCID_{50}$/mL for B/Maryland/1/59

*Note: strains used to determine analytical sensitivity (LoDs) for validation of the PBM BioSign Flu A+B LFA

For influenza A H1N1, all replicates produced positive results at all test levels, so additional lower levels (0.25X and 0.125X) were tested. For influenza A H3N2 and influenza B, all levels initially tested produced negative results for all three replicates. Thus, higher levels were tested until a test level produced three of three positive results. A summary of levels tested and the results at each level are presented in Table 7.

Table 7. Preliminary LFA LoD estimation results with individual LoDs highlighted in grey.

Flu Type	Test Level		Qualitative Results	
	Description	$TCID_{50}$/mL	# Positive	% Positive
FluA H1N1	0.5X	5.25E+01	3 of 3	100%
	0.25X	2.63E+01	3 of 3	100%
	0.125X	1.32E+01	0 of 3	0%
FluA H3N2	27X*	2.65E+03	3 of 3	100%
	20X	1.99E+03	0 of 3	0%
	10X	9.95E+02	0 of 3	0%
FluB	20X	3.98E+02	3 of 3	100%
	10X	1.99E+02	0 of 3	0%
	3X	5.97E+01	0 of 3	67%

*Note: LoD is lower than for confirmatory studies below (Table 8) because of an accidental miscalculation in preparation of H3N2 analyte for the range-finding study.

Confirmatory LoD testing was conducted with 20 replicates using contrived samples. The samples for the confirmatory testing were contrived using the sample procedure that was used for the preliminary study. For all three viral test strains the lowest concentration that produced at least 19 positives out of 20 samples (95%) was determined to be the LoD for each test strain (Table 8).

Table 8. LFA LoD confirmation results

Flu Type	Test Level		Qualitative Results	
	Description	$TCID_{50}$/mL	# Positive	% Positive
FluA H1N1	0.25X	2.63E+01	20 of 20	100%
FluA H3N2	40X*	3.98E+03	20 of 20	100%
FluB	20X	3.98E+02	20 of 20	100%

*Note: Confirmatory testing for FluA strain H3N2 was performed at a higher LoD than the range-finding LoD study.

In summary, the testing performed established that 2.6 $x10^1$ $TCID_{50}$/mL is the LoD for influenza A(H3N2), .4.0 $x10^3$ $TCID_{50}$/mL is the LoD for influenza A(H1N1) and 4.0 $x10^2$ $TCID_{50}$/mL is the LoD for influenza B.

Sample Stability

A. Viral Nucleic Acid Stability

Contrived samples containing influenza strains at a concentration of 2.5X LoD were prepared in pooled NWA matrix. Sample stability was evaluated in a study in which each device contained 2 mL of virus inoculum in NWA. The spiked NWA was placed in a CLEARinse CTS Wash Head, sealed in a CLEARinse CTS Transport Container and incubated at 4ºC and 27ºC. Testing of the contrived samples was conducted at time point zero to establish a baseline and again at 4 hours, 6 hours, 24 hours, and 48 hours. An aliquot of each contrived sample was tested for influenza using a Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV Cartridge. Each PCR assay was performed in triplicate for each time point and for each storage condition. Samples were not batched, and all testing was completed immediately upon removal of sample from the Wash Head following the instructions in the PI. The acceptance criteria for the stability study included a deviation of no more than +/- 3 Ct for each target at given time point from T = 0

Results of stability testing for each of the three influenza strains are shown below in Table 9.

Table 9. Specimen stability study quantitative PCR results from CTS devices

Virus and LoD	Storage Temp	Average Ct value				
		0-hr	4-hr	6-hr	24-hr	48-hr
FluA H1N1	4ºC	NT	35.6	36	36	36.7
2.5X LoD	27ºC	34.6	35.8	34.8	34.9	36.9
FluA H3N2	4ºC	NT	35.1	35.6	35.4	36
2.5X LoD	27ºC	35.4	35.6	35.8	36.1	36.4
FluB	4ºC	NT	36.7	36.1	37.8	37.0
5X LoD	27ºC	36.3	36.4	37.6	37.2	38.5

In summary, these data support the claim that samples that will be used for viral nucleic acid testing are stable when stored for 48 hours at room and refrigerated temperature.

B. Viral Antigen Stability

Contrived samples containing Influenza strains at a concentration of 2.5X LoD were prepared in pooled NWA matrix. Sample stability was evaluated in a study in which each

device contained 2 mL of virus inoculum in NWA. The spiked NWA was placed in a CLEARinse CTS Wash Head, sealed in a CLEARinse CTS Transport Container and incubated at 4ºC and 27ºC. Testing of the contrived samples was conducted at time point zero to establish a baseline and again at 4 hours, 6 hours, 24 hours, and 48 hours. An aliquot of each contrived sample was tested for influenza using a PBM BioSign Flu A + B test kit. Each LFA assay was performed in triplicate for each time point and for each storage condition. Samples were not batched, and all testing was completed immediately upon removal of sample from the Wash Head following the instructions in the PI.

Results of stability testing for each of the three influenza strains are shown below in Table 10.

Table 10. LFA Results from CTS Devices at 2.5X LoD

Virus	Storage Temp	Number of positive samples out of replicates with valid results				
		0-hr	4-hr	6-hr	24-hr	48-hr
FluA H1N1	4ºC	NT	3 of 3	3 of 3	3 of 3	3 of 3
	27ºC	3 of 3	3 of 3	3 of 3	3 of 3	
FluA H3N2	4ºC	NT	3 of 3	3 of 3	3 of 3	3 of 3
	27ºC	3 of 3	3 of 3	3 of 3	3 of 3	
FluB	4ºC	NT	3 of 3	3 of 3	3 of 3	3 of 3
	27ºC	3 of 3	3 of 3	3 of 3	3 of 3	

In summary, these data support the claim that samples that will be used for antigen testing are stable when stored for 24 hours at room temperature or 48 hours refrigerated.

Conclusion:
The CLEARinse CTS device does not raise different questions regarding safety and effectiveness as compared to predicate device. The proposed device is as safe, as effective, and performs as well as or better than the predicate device. The information submitted in this premarket notification supports a substantial equivalence decision.