DE NOVO CLASSIFICATION REQUEST FOR NEOASIS

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Active noise attenuation system for infant incubators. A device system which captures the environmental noise and outputs noise cancelling acoustic sound waves to attenuate noise in infant incubators in the healthcare environment.

NEW REGULATION NUMBER: 21 CFR 880.5405

CLASSIFICATION: Class II

PRODUCT CODE: QWX

BACKGROUND

DEVICE NAME: Neoasis

SUBMISSION NUMBER: DEN220048

DATE DE NOVO RECEIVED: July 25, 2022

SPONSOR INFORMATION:
Invictus Medical, Inc.
16601 Blanco Road, Suite 120
San Antonio, TX 78232

INDICATIONS FOR USE

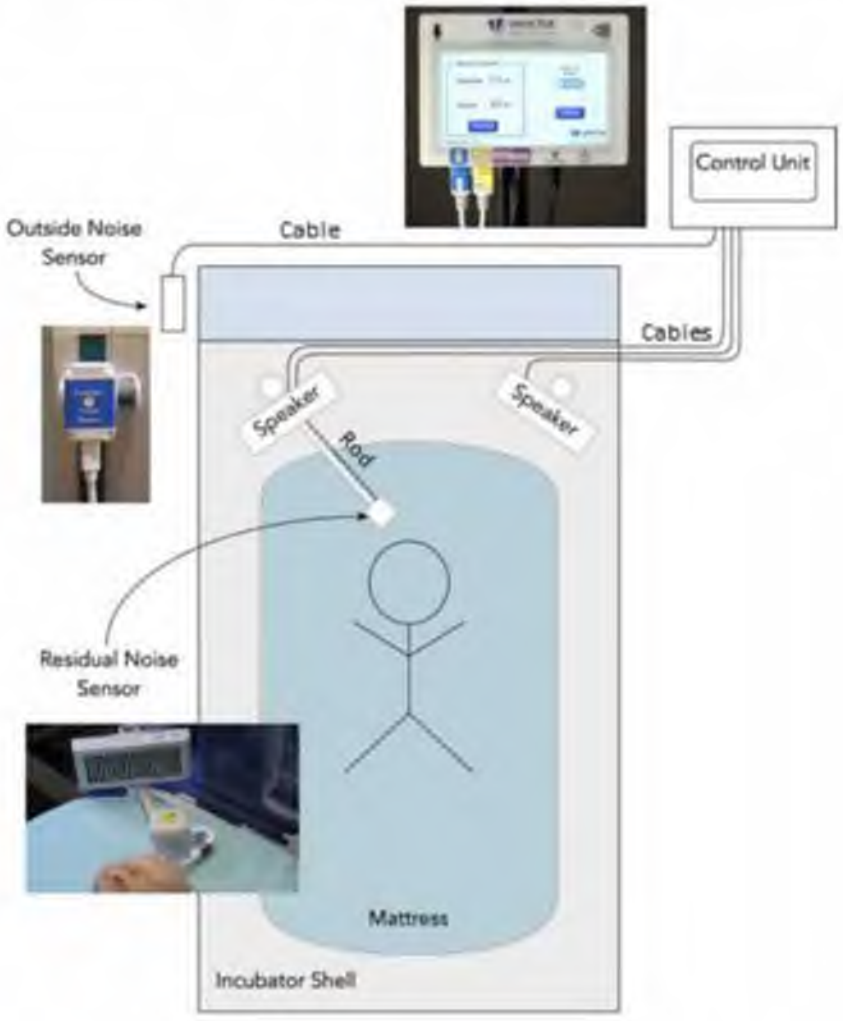
The Neoasis® device is intended to reduce noise levels inside an infant incubator in the neonatal intensive care unit (NICU). The attenuation performance of the device is for noises in the NICU with frequencies between 250 Hz to 1,000 Hz.

LIMITATIONS

- The sale, distribution, and use of the Neoasis is restricted to prescription use in accordance with 21 CFR 801.109.
- The Neoasis® is only intended for use in the GE Healthcare Giraffe OmniBed Incubator.
- All disposable accessories are intended to be used on a single patient only. None of the items that are used inside the incubator should be used with more than one patient.
- All incubator cables must be secured and away from the infant.
- Use only the power supply provided by manufacturer
- The accessories including the *speakers* should never be connected to any device except as provided by Invictus Medical.

DEVICE DESCRIPTION

The Neoasis is comprised of an outside noise sensor, a control unit, two speakers, and a residual noise sensor. All components are connected to the control unit with different cables. The outside noise sensor captures the environmental noise and transmits the information to the control unit. The control unit determines if the noise should be attenuated and contains a software algorithm which calculates the sound wave necessary to cancel out the environmental noise. If cancelation is appropriate, the control unit plays the corresponding sound wave through the speakers inside of the incubator, attenuating the noise via deconstructive interference. The residual noise sensor then captures the resulting noise inside of the incubator and communicates it to the control unit. Additionally, the device contains a voice pass through feature which allows parents or healthcare practitioners to communicate with the infant from the outside using the control unit and speakers.



SUMMARY OF NONCLINICAL/BENCH STUDIES

SOFTWARE

The Neoasis device contains software to control and determine if an external noise is appropriate for the device to attenuate based on noise characteristics (duration, wavelength, sound level), calculates the appropriate waveform needed to match the external noise waveform to reduce noise and incorporates safeguards which ensure that an incorrect waveform or an unnecessarily high volume noise is not produced. The device outputs the calculated waveform through the speakers to cancels out the environmental noise. Software verification, validation and analysis was performed, and the results demonstrate that the software functions as intended, and the required specifications are met. The software/firmware was reviewed according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. The software has a moderate level of concern.

A cybersecurity evaluation was not needed as the device does not connect to external networks or devices.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The Neoasis device conforms to the requirements for electrical safety and electromagnetic compatibility of the following standards:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) **Medical electrical equipment – Part 1: General requirements for basic safety and essential performance**
- IEC 60601-1-2:2014. **Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests**
- IEC 60950-1 Information technology equipment – Safety – **Part 1: General requirements**

BIOCOMPATIBILITY

The Neoasis device is classified as intact skin contacting with a transient contact duration. Biocompatibility was evaluated in accordance with ISO 10993-1:2018, Biological evaluation of medical devices and FDA Guidance: Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". Invictus Medical provided material information and a description of the manufacturing processes in lieu of biocompatibility testing to support the biological safety of the device. The results of these evaluations support that the biological risks of the device have been adequately mitigated.

PERFORMANCE TESTING-BENCH

The performance of the Neoasis was compared against a 510k cleared passive noise attenuation device, the MiniMuffs (K935160) in a nonclinical bench testing which simulated use with both devices on an infant mannequin. To assess the noise attenuation performance under simulated clinical use conditions, Invictus Medical used various sound sources that are present in a typical NICU setting and a mannequin with noise sensors (microphones) to evaluate the noise attenuation. The testing also evaluated situations where the infant could move to different positions within the infant incubator by providing attenuation mapping across representative locations inside of the incubator. The table below (Table 1) provides a summary of the test results and is ordered in terms of best attenuation to worst attenuation sequences. Noise attenuation is represented by the number of decibels where a positive number represents a reduction/attenuation of noise and negative numbers represent an increase/amplification of noise at the indicated frequency bands. Note that the alarm priority denotes the alarm sound from each device. Some devices play different sounds based on the alarm level, which is determined by the severity of issues. Testing the various alarm priority levels is representative of the possible alarms that the device could play in a clinical setting.

Table 1: Performance Testing – Attenuation Comparison

Alarm Device	Alarm Brand	Alarm Priority	Octave Band (Hz)	Neoasis Attenuation (dB)	Earmuffs Adhered Over Mannequin Ears Attenuation (dB)	Earmuffs Adhered Over Mannequin Ears and Human Hair Attenuation (dB)
Patient Monitor	Philips	High	125	0.49	-0.72	-1.19
			250	0.3	-0.05	-0.12
			500	1.32	1.37	0.17
			1000	11.68	3.44	-1.27
			2000	1.23	1.8	0.2
			4000	0.44	1.73	1.23
			8000	-0.19	0.02	0.01
Ventilator	Maquet	Medium	125	0.35	-1.59	0.1
			250	3.18	3.18	1.01
			500	9.38	7.45	2.54
			1000	0.14	2.35	0.6
			2000	-0.02	0.33	-1.39

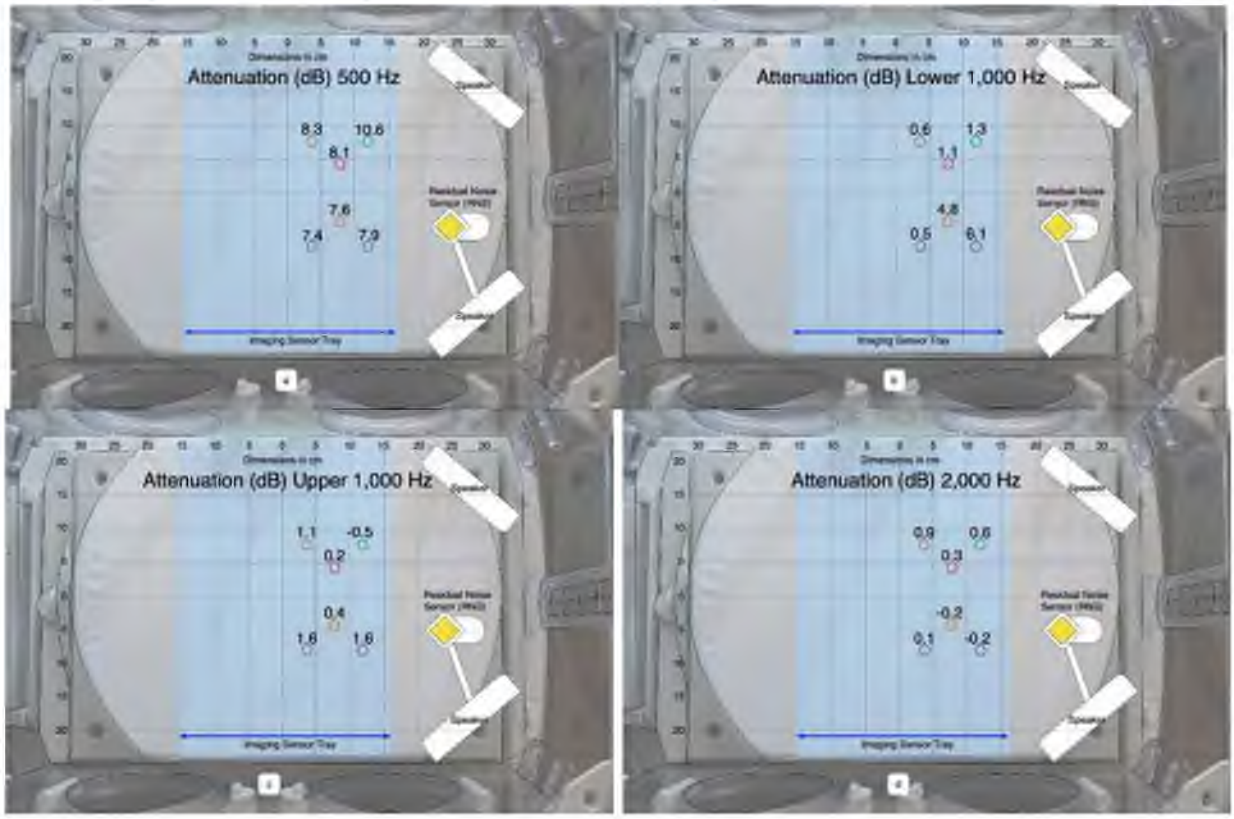
Alarm Device	Alarm Brand	Alarm Priority	Octave Band (Hz)	Neoasis Attenuation (dB)	Earmuffs Adhered Over Mannequin Ears Attenuation (dB)	Earmuffs Adhered Over Mannequin Ears and Human Hair Attenuation (dB)
			4000	0.01	0.15	-0.04
			8000	-0.02	0.02	0.01
Ventilator	Maquet	High	125	-0.12	-0.69	-0.16
			250	5.07	1.93	1.06
			500	8.64	2.43	1.36
			1000	0.6	2.64	0.45
			2000	0.16	0.76	-1.64
			4000	0.07	0.3	-0.31
			8000	-0.05	0.02	-0.13
Syringe Pump Ventilator	Medfusion Maquet	High High	125	-0.66	-0.39	-0.13
			250	3.5	1.39	0.44
			500	7	1.14	0.58
			1000	0.35	4.36	-0.05
			2000	0.3	3.03	-0.09
			4000	0.11	0.88	0.27
			8000	-0.21	0.09	-0.15
Syringe Pump Ventilator Patient Monitor	Medfusion Maquet Philips	High High High	125	-0.76	-1.74	-0.96
			250	1.44	0.27	0.31
			500	6.52	5.03	5.39
			1000	1.49	-0.29	0.53
			2000	0.45	0.58	-0.27
			4000	-0.13	1.86	-0.66
			8000	-0.43	0.06	0.04
Syringe Pump Ventilator	Medfusion Maquet	Low High	125	-0.09	-0.26	-0.83
			250	2.12	0.89	0.3
			500	5.07	0.2	0.5
			1000	-0.18	2.42	1.06
			2000	-0.27	1.94	0.2
			4000	-0.05	0.42	0.39
			8000	-0.24	0.04	-0.11
Male and	N/A	N/A	125	-0.05	-0.06	0.35

Alarm Device	Alarm Brand	Alarm Priority	Octave Band (Hz)	Neoasis Attenuation (dB)	Earmuffs Adhered Over Mannequin Ears Attenuation (dB)	Earmuffs Adhered Over Mannequin Ears and Human Hair Attenuation (dB)
Female Voices			250	-0.02	1.2	-0.18
			500	-0.01	4.7	0.98
			1000	0.13	1.66	0.03
			2000	0	0.31	-1.16
			4000	0.02	0.09	0.02
			8000	0.01	0.03	0.01
Syringe Pump Patient Monitor	Medfusion Philips	High Medium	125	-0.31	-0.55	-0.56
			250	0.75	1.04	0.07
			500	3.31	2.69	1.64
			1000	-0.92	0.22	-0.78
			2000	-0.83	0.08	-1.35
			4000	0.37	0.09	-0.86
			8000	-0.07	0.06	0.02
Patient Monitor	Philips	Medium	125	-0.21	0.07	0.04
			250	-0.15	0.35	0.31
			500	-0.13	2.04	1.97
			1000	0.13	-0.12	0.65
			2000	0.04	-0.07	0.55
			4000	-0.03	0.03	0.02
			8000	-0.12	0.02	0
Syringe Pump	Medfusion	Low	125	0.12	-0.99	-0.63
			250	-0.1	-0.05	-0.04
			500	0	1.46	1.11
			1000	-0.04	0.44	-0.05
			2000	-0.01	-0.01	-1.6
			4000	0	0.04	-0.64
			8000	0.02	0.04	0.03
Syringe Pump	Medfusion	High	125	0.07	-0.59	-0.31
			250	0.01	0.41	0.04
			500	0.03	1.95	1.15
			1000	-0.04	0.84	-1.51

Alarm Device	Alarm Brand	Alarm Priority	Octave Band (Hz)	Neoasis Attenuation (dB)	Earmuffs Adhered Over Mannequin Ears Attenuation (dB)	Earmuffs Adhered Over Mannequin Ears and Human Hair Attenuation (dB)
			2000	-0.3	-0.3	-2.03
			4000	-0.15	0.24	-0.9
			8000	-0.01	0.02	0.03

Additionally, Invictus Medical moved the noise sensing mannequin into different locations within the infant incubator to account for the potential movement of real infants. The attenuation performance study described above evaluates the changes in performance within different locations of the incubator. This resulted in an attenuation map which demonstrates the device performance at different locations in the incubator. See below for a summary of locations tested.

Figure 1: Attenuation Mapping Results by Octave Band



As shown in the results table above, within the 250-1000 hz range, the Neoasis and MiniMuffs device demonstrate similar attenuation performance. Representative positions were also tested in order to accommodate infant movement and account for performance differences based on location using a mannequin. These different positions tested are represented by the different colored circles in the incubator above. The numbers above the open circles represent the sound attenuation measured in decibels for the loudest ear of the mannequin across different locations when using the Neoasis device. The results indicate that the device performs as intended, with similar attenuation levels compared to the MiniMuffs. Based on the above testing results, the attenuation performance of the Neoasis device is similar to that of the MiniMuffs device.

REPROCESSING AND SHELF LIFE

The Neoasis is not provided sterile. Performance testing with accelerated aging confirmed the Neoasis maintained device performance over the 6 month labeled shelf life. Invictus Medical provided reprocessing and disinfection instructions to the end user which were evaluated per the 2015 FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" under clinical worst-case conditions. Cleaning and disinfection validation was provided and met the recommendations of the guidance above.

SUMMARY OF CLINICAL INFORMATION

No clinical testing was performed to support the submission. Instead, literature was relied on to support the developmental, sleep, and health benefits associated with noise reduction for infants in the NICU from passive noise attenuation devices, like earmuffs. In addition, the American Academy for Pediatrics (AAP) recommends keeping sound levels below 45 dB and notes that higher noise environments can lead to adverse effects on the growth and neurodevelopment of neonates. Overall, it is well understood that high noise environments can lead to hearing damage, reduced sleep, and can negatively impact various physiological and behavioral states.

Invictus Medical conducted Human Factors testing by recruiting 15 nurses to assess the user's ability to set up the system and place the infant correctly. The Human Factors study was carried out following FDA 2016 guidance "Applying Human Factors and Usability Engineering to Medical Devices". The participants were successful in setting up and using the Neoasis system with infants. Major tasks included attaching/setting up the device, placing the infant correctly inside the incubator, being able to read the current and past noise levels, using the talk to infant feature and handling various errors. All participants were able to complete all of the identified tasks.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

Physician labeling includes the device indications for use, a description of the device, warnings and precautions, the expected benefit of the device, and instructions for the safe and effective use of the device. The labeling instructs users to clean or, for components placed inside the incubator, clean and disinfect all parts of the device prior to use and at least weekly during use. In addition, reusable components of the device are also cleaned and disinfected between patients. The labeling satisfies the requirements of 21 CFR 801.109 Prescription devices. Per the special controls for this generic type of device, labeling includes a summary of the attenuation performance.

RISKS TO HEALTH

Table 2 identifies the risks to health that may be associated with use of an active noise attenuation system for infant incubators, and the measures necessary to mitigate these risks.

Table 2 Identified Risks to Health and Mitigation Measures

Risks to Health	Mitigation Measures
Hearing loss from high device output or ineffective device attenuation	Non-clinical performance testing Software validation, verification, and hazard analysis Electrical safety and electromagnetic compatibility testing Labeling
Infection	Labeling
Adverse tissue reaction	Biocompatibility evaluation

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, an active noise attenuation system for infant incubators is subject to the following special controls:

(1) Non-clinical performance testing under anticipated conditions of use must demonstrate that the device performs as intended, including:
   (i) Verification and validation of critical acoustic parameters, including the maximum output of the device;
   (ii) Verification and validation of the attenuation performance of the device, including:
      (A) Testing with compatible incubator model(s) and dimensions;
      (B) Attenuation performance testing simulating different infant locations and orientations within the incubator; and
      (C) Testing with relevant noise sources and room configurations.

(2) Software validation, verification, and hazard analysis must be performed.

(3) Electrical safety and electromagnetic compatibility (EMC) testing must be performed for any electrical components of the device.

(4) The patient- or user-contacting components of the device must be demonstrated to be biocompatible.

(5) Labeling for the device must include:
   (i) Instructions for infant placement and the expected attenuation performance of the device;
   (ii) Warnings regarding the risks of exposure to the potential maximum output of the device;
   (iii) Methods and instructions for cleaning and disinfection; and
   (iv) Identification of the incubator(s) that the device is intended to be used with.

BENEFIT-RISK DETERMINATION

Nonclinical laboratory studies as well as literature were used to evaluate the safety and effectiveness of the Neoasis.

Summary of Benefits

The device reduces noise at the 250-1000 Hertz range and the benefit of noise reduction for infants is well understood. Invictus Medical cites literature which concludes that there are benefits to infants from passive noise attenuation devices like earmuffs. These benefits relate to development, healing, sleep and overall health of infants in high noise environments such as the NICU. Furthermore, NIOSH guidance recommends 85 dBA for <8 hours and 100 dBA for <15 minutes to avoid hearing damage for adults. The American Academy of Pediatrics recommendation of noise level is <45db. Invictus Medical performed testing with some expected

noise sources and compared it to earmuffs. Invictus Medical has demonstrated through performance testing that the reduction in noise is comparable to passive noise canceling devices such as the MiniMuffs. Although the attenuation performance varies depending on the acoustic waveform and the environmental volume, performance testing shows approximately a 7 decibels noise reduction, which is similar to MiniMuffs.

Summary of Risks

The device is overall a low risk device. There are two probable safety risks which were identified and subsequently mitigated by Invictus Medical. Firstly, in order to attenuate noise, the device has a maximum output of 98 decibels. During use, this output would be activated when the environmental noise is high which is needed to reduce the noise levels. In addition, there are software safeguards in place to prevent the device from malfunctioning and producing noise inappropriately. Secondly, based on the way the acoustic waveforms are matched, FDA was concerned the device use may result in noise amplification. If this occurred, it would lead to the infant experiencing a higher noise than the environmental noise. However, due to the geometry and movement of the waveforms inside the incubator, it would be improbable that a noise waveforms match would lead to amplification.

Benefit/Risk Conclusion

The Neoasis performance testing demonstrates a meaningful noise attenuation, similar in impact to the cleared MiniMuffs device. Considering that device risks are mitigated through software and device performance controls, there is an overall favorable benefit-risk profile that supports granting this De Novo request.

CONCLUSION

The De Novo request for the Neoasis is granted and the device is classified as follows:

Product Code: QWX
Device Type: Active noise attenuation system for infant incubators
Regulation Number: 21 CFR 880.5405
Class: II