DE NOVO CLASSIFICATION REQUEST FOR CLEARVIEW™ SYSTEM

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Evoked Photon Image Capture Device.** An evoked photon image capture device is a prescription, electrically powered device intended for use as a non-invasive measurement tool that applies electricity to detect electrophysiological signals emanating from the skin, which are reported numerically and as images without clinical interpretation. The device is not intended for diagnostic purposes.

NEW REGULATION NUMBER: 882.1561

CLASSIFICATION: CLASS I, (Exempt from premarket notification review, subject to limitations in 21 CFR 882.9)

PRODUCT CODE: PNA

BACKGROUND

DEVICE NAME: CLEARVIEW™ SYSTEM

SUBMISSION NUMBER: DEN150004

DATE OF DE NOVO: JANUARY 13, 2015

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REQUESTER'S RECOMMENDED CLASSIFICATION: CLASS I, EXEMPT

INDICATIONS FOR USE

The ClearView™ System provides two sets of numbers under two different conditions, one with capacitive barrier to minimize the effect of variables such as oils and perspiration on the image and one without the capacitive barrier. The device provides numerical measures of electrophysiological signals emanating from the skin. The device is limited to use as a measurement tool and is not intended for diagnostic purposes or for influencing any clinical decisions. This device is only to be used to image and document electrophysiological signals emanating from the skin. Clinical management decisions should be made on the basis of routine clinical care and professional judgment in accordance with standard medical practice.

LIMITATIONS

The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR 801.109.

> The device is not intended for diagnostic purposes or for influencing any clinical decisions. The reported numbers have no clinical context. Clinical management decisions are not to be made on the basis of the ClearView System, but rather on the basis of routine clinical care and professional judgment.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS

RATIONALE FOR EXEMPTION

Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does meet these criteria and, therefore, premarket notification is not required for the device.

General controls provide reasonable assurance of safety and effectiveness if device manufacturers comply with such requirements, which includes current good manufacturing practice requirements (21 CFR part 820), including design controls (820.30) due to the inclusion of software, and general labeling (21 CFR part 801). Examples exceeding the limitations of exemption could include indications for diagnostic purposes, clinical decision making, or a significant change in the technological characteristics.

DEVICE DESCRIPTION

The ClearView System consists of the ClearView Device (hardware) attached to a computer/software system. The measurements are digital photographs acquired when placing a fingertip in contact with a glass electrode. A series of electrical impulses are applied to the glass electrode generating a localized electromagnetic field around the fingertip. Under the influence of this field, an image is generated. A software analysis of the images of the 10 fingers (including the thumbs) provides the inputs for an algorithm-driven Response Scale Report. The ClearView System provides numerical electrophysiological data to the healthcare professional. Any interpretation of this information is the responsibility of the healthcare professional; the device is limited to use as a measurement tool and is not intended for diagnostic purposes or for influencing any clinical decisions.

The ClearView System includes the following components: (1) ClearView Device, (2) Power cord, (3) USB external cable, (4) Electrode cover, (5) Finger shroud, (6) Reference probe, (7) Reference probe cable, (8) Reference probe shroud, (9) Instructions for Use, (10) Computer All-In-One System or Laptop with ClearView Software installed, (11) Keyboard and mouse, (12) USB hardware key, (13) Capacitive barriers, (14) Cleaning cloths, and (15) Alcohol swabs. Figure 1 below depicts the ClearView Device.

Figure 1: The ClearView Device as it is connected to the Clear View System.

The ClearView Device, All-In-One System or Laptop, and EPIC ClearView Software are intended to work only as part of the system, and not with any third-party hardware or software.

The electrode consists of a glass disc that electrically isolates the patient's finger from the voltage that is generated on the conductive bottom surface of the glass. The conductive surface is connected to a printed wiring board (PWB). The conductive glass assembly and the printed wiring board together form the electrode that is used in the creation of the electric field.

When a finger is applied to the glass, the operator initiates image capture through the ClearView Software. The ClearView Device initiates a pulsed voltage to the bottom of the glass generating a localized electromagnetic field around the finger. b(4) This light (signal) is captured by a camera. A software analysis provides the inputs for the measurement.

Two complete sets of images are generated for each patient:

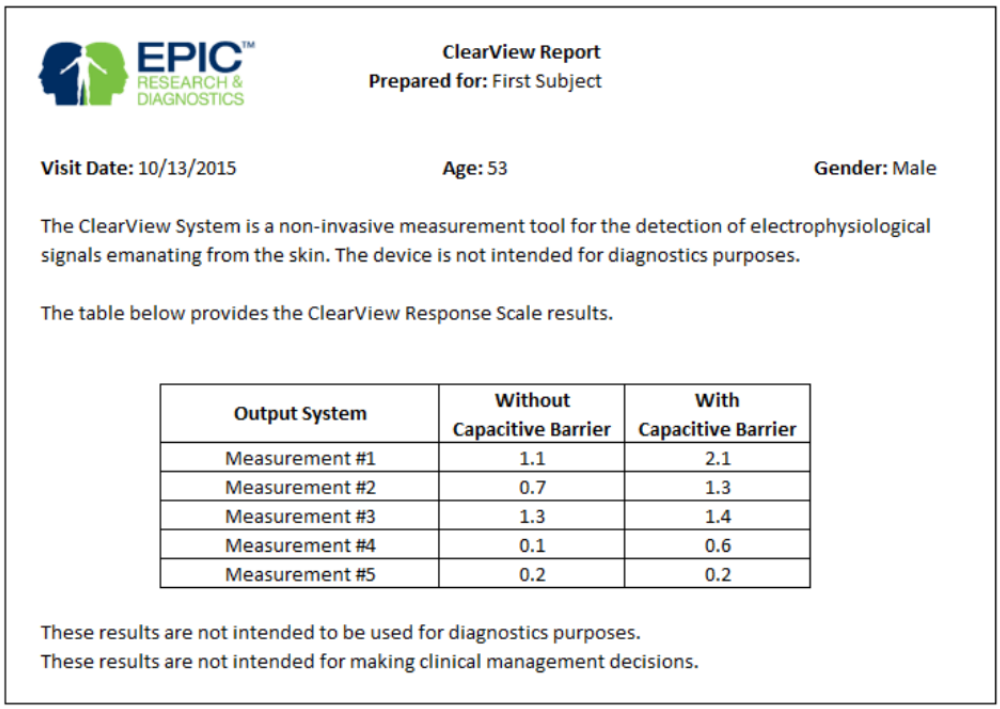
- The first sequence is captured and recorded using all ten fingers, individually placed directly on the glass.

- The second set is captured and recorded using all ten fingers, individually placed with a capacitive barrier between the finger and the glass. The capacitive barrier is designed to eliminate the body's response (perspiration and oil) from the data analysis.

The ClearView Software is designed to analyze the images collected. Each image is assigned a number of partitions and then translated into a linear waveform and the characterization data is presented through the pixel distribution and the respective correlations as it relates to each partition. Mathematical calculations are used to generate values for area and intensity of the lighted pixels. The images are further characterized through five additional mathematical coefficients, which each use area and intensity as their base. To generate the individual measurements the data is analyzed, and translated to a normalized scale (the normalized scale

does not have units associated). The data is analyzed by the ClearView Software and a report is generated.

The ClearView Report, generated by the ClearView Software, is intended to report electrophysiological scores associated with five different measurements. An example report is shown in Figure 2 below:



EPIC™ RESEARCH & DIAGNOSTICS

ClearView Report
Prepared for: First Subject

Visit Date: 10/13/2015 **Age:** 53 **Gender:** Male

The ClearView System is a non-invasive measurement tool for the detection of electrophysiological signals emanating from the skin. The device is not intended for diagnostics purposes.

The table below provides the ClearView Response Scale results.

Output System	Without Capacitive Barrier	With Capacitive Barrier
Measurement #1	1.1	2.1
Measurement #2	0.7	1.3
Measurement #3	1.3	1.4
Measurement #4	0.1	0.6
Measurement #5	0.2	0.2

These results are not intended to be used for diagnostics purposes.
These results are not intended for making clinical management decisions.

Figure 2: Example of a ClearView Report

SUMMARY OF NONCLINICAL/BENCH STUDIES

Nonclinical performance data were provided related to the following areas: biocompatibility, electrical safety, electromagnetic compatibility (EMC), and software.

BIOCOMPATIBILITY/MATERIALS

The ClearView System is a non-invasive device with limited (≤ 24 hours) contact (per ISO 10993-1 definitions); the only contact is by the intact skin on the fingertips. Several portions of the device will come into contact with the patient's intact skin for approximately five minutes for each scan session. The contacting materials are commonly found in daily use including glass, silicone, and PVC. Table 1 shows the patient's potential for contacting materials, materials of construction, and common use of the material. Because of the non-invasive contact and the everyday use of these materials, no biocompatibility testing was conducted.

Table 1: Materials Used in ClearView System

Contacting Surface Component	Material of Construction
Outer plastic housing	ABS/PC, Natural b(4))
Capacitive barrier	Specification plastic with anti-static characteristics
Electrode cover and finger shroud	URETHANE b(4)
Glass lens	Glass
Finger shroud curtains	Neoprene

ELECTROMAGNETIC COMPATIBILITY (EMC)

EMC testing was performed on the ClearView System in accordance with IEC 60601-1-2: 2007, EN 61000-4-2:2008 Electrostatic Discharge (ESD), EN 61000-4-3:2008 Radiated, Radio Frequency, Electromagnetic Field Immunity Test, EN 61000-4-4:2004 Electrical Fast Transient/Burst Immunity Test (EFT), EN 61000-4-5:2005 Surge Immunity Test (Mains), EN 61000-4-6:2008 Immunity to Conducted Disturbances, Induced by Radio Frequency Fields, EN 61000-4-8:2009: Power Frequency Magnetic Field Immunity, and EN 61000-4-11:2004 Voltage Dips, Short Interruptions and Voltage Variations Immunity. It was also tested to the following emissions standards: EN 55011-2007 (CISPR-11) Radiated Emission, EN 55011-2007 (CISPR-11) Conducted Emission, EN 61000-3-2:2009 Limits for Harmonic Current Emission <16A , EN 61000-3-3:2008, and Limitations of Voltage Fluctuations and Flicker in Low-Voltage Supply Systems >16A.

ELECTRICAL SAFETY

Electrical safety testing was performed on the ClearView System in accordance with: IEC 60601-1: 1988, IEC 60601-1: Amendment 1 (1991), and IEC 60601-1: Amendment 2 (1995). Note that testing from the most recent third addition of IEC 60601-1 (Design Reviews and Risk Analysis) was deemed unnecessary because the physical testing of the device according to the version standard to which the device was tested is adequate to ensure safety for this device and because of the low risk of the device.

SOFTWARE

The software for the ClearView System presents a "minor" level of concern based on answers to questions listed in FDA's *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 11, 2005). Adequate documentation has been provided.

SUMMARY OF CLINICAL INFORMATION

A prospectively enrolled, single center, randomized study was performed to assess the repeatability and reproducibility of the ClearView Scanner to demonstrate the reliability of the ClearView System measurements.

Eligibility Criteria

Subjects were recruited internally from the study site. Family and friends of staff members were screened and enrolled as long as they met all inclusionary and no exclusionary criteria. Site employees directly involved with the study and their family members were ineligible. Potential subjects were screened for age and availability. Pregnant or potentially pregnant women, anyone with implanted cardiac or electrical scanners or loss of part of any finger were excluded.

Protocol

Three trained and certified EPIC employees were designated ClearView Scanning operators. These operators were assigned a ClearView Scanner and were considered an operator-scanner pair for statistical analysis. Subjects were screened for eligibility and enrolled if criteria were met. All subjects were consented in accordance with the Declaration of Helinski, ICH GCP, US Code of Regulations for Protection of Human Subjects (21 CFR 50.25, CFR 50. 27, and CFR Part 56 Subpart A), the Health Insurance Portability and Accountability Act (HIPAA), and local regulations. Subjects were randomly scanned consecutively on three different ClearView Scanners (Scanners 100, 102, 10E) with three different operators (operator-scanner pair #1, #2, #3). Each subject was scanned twice on all three ClearView Scanners on both Day 1 and Day 2 of the study. Between scans on the same operator-scanner, each subject stepped away from the scanner for at least 20 seconds, than were repositioned for a subsequent scan. Subjects had 10 fingers measured; twice with a capacitive (filter) barrier and twice without a capacitive barrier, for a total of 40 images at each operator-scanner. This procedure was completed by all subjects on all three operator-scanners. On Day 2 all subjects followed the same procedure. The order in which subjects were scanned and order of operator-scanner scanning was randomized and documented for both Day 1 and Day 2.

Sample Size/Test Frequency Determination

The sample size calculation to assess the repeatability and reproducibility of ClearView Response Scale was based on Intraclass Correlation Coefficient (ICC). A sample size of 18 subjects with 2 repeated scans per subject achieves 80% power to detect an expected ICC of 0.80 or greater when the null ICC is 0.50 with significance level of 0.05 (Walter et al, 1998). This sample size of 18 subjects was calculated to evaluate the reliability of 3 operators-scanner pairs, and across 2 days.

Results

Nine (9) males and nine (9) females were screened and enrolled. Ages ranged from 23 to 77 years of age for females and 32 to 65 years of age for males, and were ethnically diverse. All 18 subjects completed all required 12 scans across two days, giving a total of 216 scans in this study.

There were no known or reported Adverse Events (AE) that occurred during the study and no occurrence of any unanticipated or anticipated adverse scanner effects.

Reliability of measurement scores was assessed by Coefficient of Variation and Intraclass (Interclass) Correlation Coefficients (ICC). The coefficient of variation was calculated as the residual standard deviation from the repeated measures ANOVA fitted with subject and each factor (operator-scanner pair and day) as random effects and divided by the mean of each measurement score, with and without barrier. The ICCs were calculated from repeated measures analysis of variance (ANOVA) with subject and each factor (operator-scanner pair and day) as random effects. Inter-factor and intra-factor ICCs were derived for each measurement score, with and without barrier. Coefficients of variations were summarized in Table 2 and Table 3 for reliability by operator-scanner pair and by day, respectively.

Table 2: Reliability by Operator/Scanner

3 Operators	System Names	Overall Mean	Residual Variance	Coefficient of Variation
Without Barrier	Measurement 1	2.390	0.0996	0.132
	Measurement 2	2.644	0.0986	0.119
	Measurement 3	1.871	0.0012	0.019
	Measurement 4	1.330	0.0369	0.144
	Measurement 5	1.484	0.0458	0.144
With Barrier	Measurement 1	2.235	0.0977	0.140
	Measurement 2	2.093	0.0382	0.093
	Measurement 3	1.743	0.0024	0.028
	Measurement 4	1.945	0.0039	0.032
	Measurement 5	1.929	0.0659	0.133

Table 3: Reliability by Day

2 days	System Names	Overall Mean	Residual variance	Coefficient of Variation
Without Barrier	Measurement 1	2.390	0.0688	0.110
	Measurement 2	2.644	0.0898	0.113
	Measurement 3	1.871	0.0011	0.017
	Measurement 4	1.330	0.0334	0.137
	Measurement 5	1.484	0.0327	0.122
With Barrier	Measurement 1	2.235	0.1068	0.146
	Measurement 2	2.093	0.0458	0.102
	Measurement 3	1.743	0.0024	0.028
	Measurement 4	1.945	0.0046	0.035
	Measurement 5	1.929	0.0822	0.149

The average coefficient of variation by operator-scanner pair was 0.098 (95%CI: 0.061, 0.14) and the average coefficient of variation by day was 0.096 (95%CI: 0.060, 0.13). The average Inter-Operator ICC was 0.74 (95%CI: 0.65, 0.83) and the average Intra-Operator ICC was 0.77 (95%CI: 0.68, 0.87). The average Inter-Day ICC was 0.72 (95%CI: 0.62, 0.82) and the average Intra-Day ICC was 0.78 (95%CI: 0.71, 0.86).

Based on the literature, ICC between 0.4 and 0.59 is considered fair reliability; ICC between 60 and 0.74 is considered good reliability; and ICC above 0.75 is considered excellent reliability (Cicchetti, 1994 and Cicchetti and Sparrow, 1981). The ICC values in this study demonstrated good reliability of the measurement scores from ClearView. The ClearView Scanner demonstrated high repeatability and reproducibility across operators, days, and scanners, as evidenced by relatively low coefficients of variation.

LABELING

The labeling meets the requirements of 21 CFR §801.109 for prescription devices.

The following information is included in the labeling for the ClearView System: contraindications, warnings, and precautions, system description, indications for use, system set up, device calibration, how to enter patient information, how to capture images, how to generate reports, and general device care, storage, and disposal instructions.

BENEFIT/RISK DETERMINATION

The risks associated with the evoked photon image capture device are adverse tissue reaction, electromagnetic incompatibility, and electromagnetic malfunction (e.g., shock). The severity and incidence of these risks to health are relatively low due to the very limited patient contact with the device. As such, general controls are sufficient to mitigate these risks and reasonably assure safety and effectiveness. General controls include but are not limited to good manufacturing practice requirements (21 CFR part 820), including design controls (820.30) due to the inclusion of software, and general labeling (21 CFR part 801).

The probable benefits of the device are based on the ClearView™ System being a tool that provides physicians with quantified measurements of electrophysiological response associated with individual patients. The measurements reported by the ClearView Scanner demonstrated high repeatability and reproducibility. The inherent benefit associated with ClearView™ System relates to the device's ability to provide physicians immediate access to electrophysiological information on patients in a safe and noninvasive manner.

Additional factors considered in determining probable risks and benefits for the device is that it is not intended for diagnostic purposes or for influencing any clinical decisions. The reported numbers have no clinical context.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data support that for use as a non-invasive measurement tool that detects and records electrophysiological signals, the probable benefits outweigh the probable risks for the ClearView™ System.

CONCLUSION

The *de novo* request for the ClearView™ System is granted and the device is classified under the following:

Product Code: PNA
Device Type: Evoked Photon Image Capture Device
Class: Class I, (Exempt from premarket notification, subject to limitations in 21 CFR 882.9)
Regulation: 21 CFR 882.1561

REFERENCES

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Cicchetti, DV and Sparrow, SS (1981) "Developing criteria for establishing interrater reliability of specific items: Applications to assessment of adaptive behavior." *American Journal of Mental Deficiency*, 86, 127-137.

Walter, S.D., Eliasziw, M, Donner, A (1998) "Sample size and optimal designs for reliability studies." *Statistics in Medicine*. 17, 101-110.