Special 510(K) Application – VuPad Ophthalmic Ultrasound System
Section 2 – 510(K) Summary

510(K) Summary
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92

Date: March 12, 2014

1. Company and Correspondent making the submission:
   Name: Sonomed Inc.
   Address: 1979 Marcus Ave
             Lake Success, NY, 11798
             U.S.A.
   Telephone: 516-354-0900
   Fax: 516-354
   Website: www.sonomed.com
   Contact: Mr. Charles C. O’Neal, Quality Manager
   E-mail: coneal@escaletonmed.com

2. Device:
   Trade/proprietary name: VuPad
   510(k) Number: K140199
   Common Name: Diagnostic ultrasound system
   Classification Name: System, imaging, pulsed echo, ultrasonic

3. Predicate Devices:
   Manufacturer: Sonomed, Inc.
   Device: E-Z Scan 5500+ A-Scan / B-Scan System
   510(k) Number: K040668

   Manufacturer: Sonomed, Inc.
   Device: VuMax System
   510(k) Number: K060626

4. Classification Names & Citations:
   Classification: Class 2
   Classification Code: 21 CFR 892.1560, 1570, IYO, ITX, system, imaging, pulsed echo, ultrasonic

5. Description:

   The VuPad is a portable ultrasound biometric ruler intended for use in ophthalmic applications. The system allows for the measurement of several key ocular features including axial length (AXL), anterior chamber depth, and lens thickness while also aiding in the calculation of associated IOL power for implanted lenses.

   The device is used by coupling the probe / transducer to the eye either through direct contact or immersion methods. Available modes are biometric A-scan, B-scan, and UBM (high frequency B-scan).

   The A-scan mode of the system features a live A-scan trace with storage for up to five scans. There are five (auto/ manual) examination modes that use three different tissue velocities to calculate individual intraocular distances within the eye (ACD, Lens, and Vitreous). Other features include: post examination review of scans & measurement; five IOL formulas (six refractive and three post refractive) for lens power calculations; an immersion scanning capability for zero corneal compression of the eye while scanning and storage for up to five different user profiles.
Special 510(K) Application – VuPad Ophthalmic Ultrasound System
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The B-Scan mode produces a live, two-dimensional image to facilitate the identification and measurement of ocular pathologies in the posterior-chamber of the eye, particularly when view of the chamber is obscured, such as is the case with cataracts.

The VuPad is a stand-alone system that runs on a Windows 8 platform and may be networked (by the user) for interface with electronic medical records systems, printing, and other purposes. The system consists of the VuPad console, ultrasound probe(s) and transducer(s), and foot pedal.

6. Indications for Use:
The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

7. Comparison with predicate device:
Sonomed, Inc. believes that the technologies incorporated into the VuPad are substantially equivalent to those of the E-Z Scan 5500+ A-scan / B-scan system and the VuMax System.

A summary listing of design characteristics that are shared between the VuPad and the established predicate devices is provided on the following pages.

A summary listing of design characteristics that differ between the VuPad and the established predicate devices is also provided on the following pages.
**Special 510(K) Application – VuPad Ophthalmic Ultrasound System**  
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A summary listing of VuPad design characteristics that are the same as established predicate devices is provided below:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>VuPad</th>
<th>EZScan AB5500+</th>
<th>VuMax</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Similarities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.</td>
<td>The EZ Scan ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.</td>
<td>The VuMAX ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye.</td>
</tr>
<tr>
<td><strong>Ultrasound Modes</strong></td>
<td>Ophthalmic A and B Scans</td>
<td>Ophthalmic A and B Scans</td>
<td>Ophthalmic A and B Scans</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td>Visualization by Ultrasound</td>
<td>Visualization by Ultrasound</td>
<td>Visualization by Ultrasound</td>
</tr>
<tr>
<td><strong>General Method of Operation</strong></td>
<td>Echoes converted to images on a screen. Measurement made by time delays</td>
<td>Echoes converted to images on a screen. Measurement made by time delays</td>
<td>Echoes converted to images on a screen. Measurement made by time delays</td>
</tr>
<tr>
<td><strong>Digital System</strong></td>
<td>Echoes converted into digital pulses, all operation carried out digitally</td>
<td>Echoes converted into digital pulses, all operation carried out digitally</td>
<td>Echoes converted into digital pulses, all operation carried out digitally</td>
</tr>
<tr>
<td><strong>Ability To Make Measurements</strong></td>
<td>Can make measurements using A-scan technology</td>
<td>Can make measurements using A-scan technology</td>
<td>Can make measurements using A-scan technology</td>
</tr>
<tr>
<td><strong>Eye-transducer Interface</strong></td>
<td>Sealed probes with scanning transducer behind ultrasound transparent membrane (10, 12.5, 20 MHz); and Stand-off or &quot;nose-scone&quot; separates exposed transducer from patient (35, 50 MHz)</td>
<td>Sealed probes with scanning transducer behind ultrasound transparent membrane (10 MHz)</td>
<td>Stand-off or &quot;nose-scone&quot; separates exposed transducer from patient (35, 50 MHz)</td>
</tr>
<tr>
<td><strong>IOL Power Calculation</strong></td>
<td>Various formulas available</td>
<td>Various formulas available</td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Method of generating A-Scans</strong></td>
<td>Separate A-Scan transducer, A-scan measuring system</td>
<td>Separate A-Scan transducer, A-scan measuring system</td>
<td>Line traced on B-Scan, A-scan shown, caliper for measurement</td>
</tr>
<tr>
<td><strong>Focus feature</strong></td>
<td>Improves resolution by reducing transducer ringing by software</td>
<td>Not available.</td>
<td>Improves resolution by reducing transducer ringing by software</td>
</tr>
<tr>
<td><strong>A-Scan Probe Design</strong></td>
<td>Closed Fixed Single-Element with Internal Fixation Light</td>
<td>Closed Fixed Single-Element with Internal Fixation Light</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Section 2 – 510(K) Summary

<table>
<thead>
<tr>
<th>Parameter</th>
<th>VuPad (K140199)</th>
<th>EZScan AB5500+ (K040066B)</th>
<th>VuMax (K060526)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Similarities (cont.)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-Scan Transducer Frequency</td>
<td>10 MHz</td>
<td>10 MHz</td>
<td>N/A</td>
</tr>
<tr>
<td>A-Scan Available Probe Configurations</td>
<td>Solid Tip (for immersion scan)</td>
<td>Solid Tip (for immersion scan)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Soft-Touch (for direct contact scan)</td>
<td>Soft-Touch (for direct contact scan)</td>
<td></td>
</tr>
<tr>
<td>A-Scan Measurements</td>
<td>Anterior Chamber Depth</td>
<td>Anterior Chamber Depth Lens Thickness Axial Length Manual Measurements</td>
<td>N/A</td>
</tr>
<tr>
<td>A-Scan Measurement Accuracy</td>
<td>±0.1 mm (clinical)</td>
<td>±0.1 mm (clinical)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>±0.02 mm (theoretical)</td>
<td>±0.023 mm (theoretical)</td>
<td></td>
</tr>
<tr>
<td>A-Scan Measurement Range</td>
<td>18 - 40 mm</td>
<td>18 - 40 mm</td>
<td>N/A</td>
</tr>
<tr>
<td>A-Scan IOL Formulas</td>
<td>Holladay Regression-II Theoretic-T Binkhorst Hoffer-Q Haigis Latkany Mypoic Post-Refractive Latkany Hyperoptic Post-Refractive Aramberri Double-K Post-Refractive</td>
<td>Holladay Regression-II Theoretic-T Binkhorst Hoffer-Q Haigis Latkany Mypoic Post-Refractive Latkany Hyperoptic Post-Refractive Aramberri Double-K Post-Refractive</td>
<td>N/A</td>
</tr>
<tr>
<td>A-Scan Tissue Velocity Constants</td>
<td>Anterior Chamber Lens Vitreous</td>
<td>Anterior Chamber Lens Vitreous</td>
<td>N/A</td>
</tr>
<tr>
<td>A-Scan User Constants</td>
<td>Personalized A-Constants Surgeon Factors</td>
<td>Personalized A-Constants Surgeon Factors</td>
<td>N/A</td>
</tr>
<tr>
<td>A-Scan Acoustic Output Global Maximum</td>
<td>$I_{PTA,3} &lt; 50 \text{ mW/cm}^2$ $M I &lt; 0.23$</td>
<td>$I_{PTA,3} &lt; 50 \text{ mW/cm}^2$ $M I &lt; 0.23$</td>
<td>N/A</td>
</tr>
<tr>
<td>B-Scan Lines per Scan</td>
<td>256</td>
<td>128 or 256</td>
<td>256</td>
</tr>
<tr>
<td>Selectable A-Scan Vector while in B-Scan mode</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Sonomed, Inc
1979 Marcus Avenue  Lake Success, NY 11042, USA
Tel 800-227-1285 / 516-354-0900  Fax 516-354-5902
### Section 2 – 510(K) Summary

<table>
<thead>
<tr>
<th>Parameter</th>
<th>VuPad (K140199)</th>
<th>EZScan AB5500+ (K040668)</th>
<th>VuMax (K060626)</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-Scan Scan Display Controls</td>
<td>Fully adjustable time-varied gain (TVG), baseline, log gain, and exponential gain</td>
<td>Fully adjustable time-varied gain (TVG), log gain, and exponential gain</td>
<td>Fully adjustable time-varied gain (TVG), baseline, log gain, and exponential gain</td>
</tr>
<tr>
<td>B-Scan Video Clips</td>
<td>Capture and store 50-frame video clips</td>
<td>N/A</td>
<td>Capture and store 50-frame video clips</td>
</tr>
</tbody>
</table>
A summary listing of VuPad design characteristics that differ from established predicate devices is provided below:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>VuPad</th>
<th>EZScan AB5500+ K04068</th>
<th>VuMax</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Differences</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hardware Configuration and Components</td>
<td>System consists of unit with integrated LCD touch screen, A-probe, sealed B-probe, open transducer water path B-probe, calibration cylinder, probe holder, and foot pedal</td>
<td>System consists of unit with integrated LCD touch screen, A-probe, sealed B-probe, calibration cylinder, probe holder, and foot pedal</td>
<td>Systems consists of tower PC with integrated ultrasound electronics, PC monitor, open transducer water path B-probe, keyboard, mouse, and foot pedal</td>
</tr>
<tr>
<td>Control Interface</td>
<td>Operator uses tablet PC with LCD touch screen and foot pedal to collect exam data.</td>
<td>Operator uses LCD touch screen and foot pedal switch to collect exam data.</td>
<td>Operator uses desktop computer control interface to collect exam data. Hardware includes monitor, keyboard, mouse, and foot pedal switch.</td>
</tr>
<tr>
<td>System Dimensions</td>
<td>13.3&quot; x 8.0&quot; x 2.0&quot;</td>
<td>9.4&quot; x 8.9&quot; x 2.8&quot;</td>
<td>Dimensions vary for multiple components</td>
</tr>
<tr>
<td>Display Screen</td>
<td>Integrated LCD Panel (10.1&quot; diagonal wide-screen, 1920 x 1080 pixel resolution)</td>
<td>Integrated LCD Panel (5.25&quot; x 3.4&quot;, 640x480)</td>
<td>PC Monitor (17&quot; Diagonal, 1280 x 1024 pixel resolution)</td>
</tr>
<tr>
<td>Data Storage Location</td>
<td>Storage within software database with ability to recall patient exam records</td>
<td>Internal storage of a single patient exam (previous exam data overwritten when new exam initiated) Capability to export exam record to PC via serial connector for long-term storage</td>
<td>Storage within software database with ability to recall patient exam records</td>
</tr>
<tr>
<td>Printer</td>
<td>Any Windows-compatible printer (separate)</td>
<td>Sony UP-897MD video printer (separate)</td>
<td>Any Windows-compatible printer (separate)</td>
</tr>
<tr>
<td>A-Scan Measurement Accuracy</td>
<td>±0.1 mm (clinical) ±0.02 mm (theoretical)</td>
<td>±0.1 mm (clinical) ±0.023 mm (theoretical)</td>
<td>N/A</td>
</tr>
<tr>
<td>B-Scan Transducer Frequencies</td>
<td>12.5 MHz, 20 MHz, 35 MHz, 50MHz</td>
<td>10MHz</td>
<td>35 MHz, 50MHz</td>
</tr>
<tr>
<td>B-Scan Transducer drive and receiver</td>
<td>Circuitry suitable for 12.5-50MHz</td>
<td>Circuitry suitable for 10MHz</td>
<td>Circuitry suitable for 10-50 MHz</td>
</tr>
<tr>
<td>B-Scan Axial Accuracy (Theoretical)</td>
<td>12.5 MHz: 0.2034 mm 35 or 50 MHz: 0.0146mm</td>
<td>10 MHz: 0.2088 mm</td>
<td>35 or 50 MHz: 0.0146mm</td>
</tr>
</tbody>
</table>

Sonomed, Inc
1979 Marcus Avenue Lake Success, NY 11042, USA
Tel 800-227-1285 / 516-354-0900 Fax 516-354-5902
8. Conclusions:
The goal in designing the VuPad system was to combine the primary features of two previously marketed predicate devices into a single self-contained package along with enhancements in ergonomics and utility that embody the current state of the industry.

The core technologies incorporated into the VuPad are primarily based on two predicate devices that are currently legally marketed by Sonomed, Inc: the E-Z Scan 5500+ A-Scan / B-Scan system (K040668) and the VuMax System (K060626). The similarities in intended usage, method of application, and system capability between the VuPad and predicate devices are evidenced in the comparison tables provided herein.

Both the E-Z Scan 5500+ A/B system and the VuPad system provide Operators with a combination of B-scan and A-scan ultrasound. The A-scan technology incorporated into the VuPad system is fundamentally identical to that currently in use by the E-Z Scan 5500+ A/B system.

Similarly, the Ultrasound Biomicroscopy (UBM) capabilities of the VuPad System are fundamentally identical to that of the VuMAX. The VuPad utilizes the exact same models of 35Mhz and 50Mhz transducers as the VuMAX system to collect live B-scan images of the anterior segment of the eye. The intended usage and method of application for these transducers are the same for both systems.

The VuPad also provides users with the additional option of using 12.5 MHz or 20 MHz B-scan transducers for enhanced B-Scan imaging of the posterior segment of the eye. The intended use and application of these transducers are exactly the same as the 10 MHz B-scan transducer provided for use with the previously cleared E-Z Scan AB5500+. The dual transducer frequencies made available with the VuPad system (12.5 MHz and 20 MHz) provide users with superior image resolution and greater exam flexibility while maintaining a comparable scanning depth when compared to the use of a single 10 MHz transducer.

The differences in Hardware Configuration, Control Interface, System Dimensions, Display Screen, Data Storage Location, and Printing Capability evident in the VuPad system do not render the device substantially different from the predicate devices because they do not establish a new intended usage, nor do they significantly alter the core A-scan and B-scan scan technologies employed by the system. These variances in form factor and data presentation have been evaluated by Sonomed's Risk Management Team and shall be addressed and fully detailed within the Operator's Instruction Manual that shall accompany the system.

In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification Sonomed, Inc. has concluded that the VuPad is safe and effective and substantially equivalent to predicate devices as described herein.

9. Safety, EMC and Performance Data:
   Electrical, mechanical, environments safety and performance testing according to standard IEC 60601-1, IEC 60601-2-37, and EN/IEC 60601-1-2(2001) are currently pending.

10. Sonomed Inc. will update and include in this summary any other information deemed reasonably necessary by the FDA.
Sonomed, Inc.
% Mr. Charles O'Neal
Quality Manager
1979 Marcus Avenue, Suite 105C
LAKE SUCCESS NY 11042

Re: K140199
Trade/Device Name: VuPad
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: March 12, 2014
Received: March 20, 2014

Dear Mr. O'Neal:

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 Part 801); 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 regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

[Signature]

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer: 10 MHz

### 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)

### DEVELOPMENT OF HEALTH AND HUMAN SERVICES

**Indications for Use**

Device Name
VuPad

**Indications for Use (Describe)**

The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer: 10 MHz

### Clinical Application

<table>
<thead>
<tr>
<th>General (Track 1 Only)</th>
<th>Specific (Tracks 1 &amp; 3)</th>
<th>B</th>
<th>M</th>
<th>PWD</th>
<th>CWD</th>
<th>Color Doppler</th>
<th>Combined (Specify)</th>
<th>Other* (Specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic</td>
<td>Ophthalmic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Mode of Operation

A Mode (NEW)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRASStaff@fda.hhs.gov

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**Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)**

[Signature]

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**Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)**

[Signature]
Indications for Use

The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application. It is intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer: 12.5 MHz

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>General (Track 1 Only)</td>
<td>Specific (Tracks 1 &amp; 3)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Ophthalmic</td>
</tr>
</tbody>
</table>

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)

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FORM FDA 3881 (1/14)  
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Indications for Use

The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer: 20 Mhz

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>General (Track 1 Only)</td>
<td>Specfic (Tracks 1 &amp; 2)</td>
</tr>
<tr>
<td>Ophthalmic</td>
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</tr>
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Type of Use (Select one or both, as applicable)

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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Indications for Use

Device Name
VuPad

Indications for Use (Describe)
The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer: 35 Mhz

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation</th>
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</thead>
<tbody>
<tr>
<td>General (Track 1 Only)</td>
<td>Specific (Tracks 1 &amp; 3)</td>
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<tr>
<td>Ophthalmic</td>
<td>Ophthalmic</td>
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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)

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**Indications for Use**

The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

**System:** VuPad  
**Transducer:** 50 MHz

### Clinical Application

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<th>PWD</th>
<th>CWD</th>
<th>Color Doppler</th>
<th>Combined (Specify)</th>
<th>Other* (Specify)</th>
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</table>

**Type of Use (Select one or both, as applicable)**  
- [x] Prescription Use (Part 21 CFR 801 Subpart D)  
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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