October 2, 2019

Neocis Inc.
Thomas E. Claiborne, Ph.D.
Regulatory Affairs Manager
2800 Biscayne Blvd Suite 600
Miami, Florida 33137

Re: K191363
Trade/Device Name: Neocis Planning Software Application (NPSA) for 3rd Party PCs
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: PLV
Dated: August 28, 2019
Received: September 3, 2019

Dear Thomas E. Claiborne:

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); 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.


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,

Michael E. Adnodha -S
for Srinivas Nandkumar, Ph.D.
Acting Division Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Neocis Planning Software Application (NPSA) for 3rd Party PCs is intended to perform the planning (pre-operative) phase of dental implantation surgery. The NPSA provides pre-operative planning for dental implantation procedures. The output of the NPSA is to be used with the Neocis Guidance System.

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.

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

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510(k) Summary

I. Submitter
Neocis Inc.
2800 Biscayne Blvd.
Suite 600
Miami, FL 33137
Tel: 1-855-9NEOCIS

Contact Person: Thomas Claiborne, Ph.D., Regulatory Affairs Manager
Date Prepared: October 1, 2019

II. Device
Trade Name: Neocis Planning Software Application (NPSA) for 3rd Party PCs
Common Name: Dental Stereotaxic Instrument
Classification Name: Bone cutting instrument and accessories (21 CFR 872.4120)
Classification: Class II
Product Code: PLV

III. Predicate Devices
- Neocis Guidance System (NGS) (K182776)

IV. Indications for Use
The Neocis Planning Software Application (NPSA) for 3rd Party PCs is intended to perform the planning (pre-operative) phase of dental implantation surgery. The NPSA provides pre-operative planning for dental implantation procedures. The output of the NPSA is to be used with the Neocis Guidance System.

V. Device Description
The Neocis Guidance System (NGS) is a stereotaxic medical device that guides surgeons during dental implant surgery. The system allows the user to plan the surgery virtually in software using a CT scan of the patient, and the plan is used by a guidance system to provide physical, visual, and audible feedback to the surgeon during the implant site preparation.

The Neocis Planning and Software Application (NPSA) for 3rd Party PCs is intended to facilitate dental implant procedure planning on any properly equipped PC so that procedures may be preplanned in advance of the surgical procedure. The NPSA is designed to upload CT scan images in DICOM file format, reconstruct and optimize 3D images of the patient anatomy, and plan the surgical procedure via defining implant placement location. We can install the NPSA on any personal computer (PC) that is convenient for our customers provided it is running Windows 7 Operating System (OS) or newer and meets the system requirements listed in our NPSA User Manual.

The NPSA is similar to the cleared planning and guidance software installed on the NGS Planning Station (PS). However, when the planning and guidance software is used on 3rd party PCs, the guidance features are inactive. When the preplan is uploaded to the PS, the planning and guidance software installed on the PS performs checks against a CT scan of the patient taken on the day of the procedure and uploaded to the PS. Any discrepancies would require a new plan to be made. The ability to make operative plan adjustments pre- or intraoperatively is a feature of the NGS.
VI. Comparison of Technological Characteristics

This submission is focused on the planning software as a standalone device. This submission includes minor changes to the planning software. There are no changes to the hardware (NGS).

<table>
<thead>
<tr>
<th>Technological Characteristics</th>
<th>Subject Device</th>
<th>Predicate K182776</th>
<th>SE Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use (IFU)</td>
<td>The Neocis Planning Software Application (NPSA) for 3rd Party PCs is intended to perform the planning (pre-operative) phase of dental implantation surgery. The NPSA provides pre-operative planning for dental implantation procedures. The output of the NPSA is to be used with the Neocis Guidance System.</td>
<td>The Neocis Guidance System (NGS) is a computerized navigational system intended to provide assistance in both the planning (pre-operative) and the surgical (intra-operative) phases of dental implantation surgery. The system provides accurate navigational guidance of surgical instruments, with regard to pre-operative planning in dental implantation procedures.</td>
<td>The indications for use are a subset of the predicate’s. The intended use is the same.</td>
</tr>
<tr>
<td>NGS Technology</td>
<td>No changes</td>
<td>Described in predicate</td>
<td>No differences</td>
</tr>
<tr>
<td>NPSA</td>
<td>v1.8.1 Guidance features are disabled.*</td>
<td>v1.2</td>
<td>Minor changes between versions and the guidance features were evaluated in the risk analysis and verification testing</td>
</tr>
<tr>
<td>Level of Concern</td>
<td>Moderate</td>
<td>Moderate</td>
<td>Same LOC</td>
</tr>
</tbody>
</table>

*Changes since v1.2 include minor functional updates, bug fixes, and an implant library for visualization.

VII. Performance Testing

This submission only includes the planning software. Testing for the software-NGS interactions has been omitted.

Planning Software Verification and Validation

Software and system verification and validation testing were conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this submission was considered as a “minor” level of concern, since a failure or latent flaw in the software could not directly result in result in minor injury to the patient or operator.

Software Development and Testing was performed per IEC 62304: 2006 Medical Device Software – Software Lifecycle Processes, FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and FDA General Principles of Software Validation; Final Guidance for Industry and FDA Staff (January 11, 2002).
Risk analysis was conducted in compliance with ISO 14971:2012 and includes FMEA analysis to review the following:

- risks associated with the use, usability and performance of the device (uFMEA)
- the risks associated with and specific to the design aspects of the device (dFMEA)
- the risks associated with software functionality and software interaction with the user (sFMEA)
- Cybersecurity risks (cFMEA)

The combined software and system testing and analysis of results (details in Table 2 below) provide assurance that the device performs as intended.

**Table 2: Summary of planning software V&V.**

<table>
<thead>
<tr>
<th>Software Verification / Validation Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simulated Use</td>
<td>Run through of Typical Use Case</td>
</tr>
<tr>
<td>Boundary Condition</td>
<td>Testing of all potential boundary parameters in the Application Software</td>
</tr>
<tr>
<td>Registration</td>
<td>Testing of registration process</td>
</tr>
<tr>
<td>Case File Contents</td>
<td>Simulated use testing of features associated with saving / loading Cases</td>
</tr>
<tr>
<td>Error Case Injection</td>
<td>Simulating all error messages and pop-ups.</td>
</tr>
<tr>
<td>CT Scan Verification</td>
<td>Verification of the resolution and validity of CT Scans</td>
</tr>
<tr>
<td>File Transfer</td>
<td>Verification of usability of file before and after transfer</td>
</tr>
<tr>
<td>Dental Implant Libraries</td>
<td>Verification of quality and speed of implant rendering</td>
</tr>
<tr>
<td>Generation and Visualization of 3D Reconstruction</td>
<td>Verification that all features of CT scan image reconstruction are functioning and accurate</td>
</tr>
<tr>
<td>Software Verification / Validation Type</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Installation, Stability, and Removal from 3rd Party PCs</td>
<td>Verification that the software can be installed, runs, and can be removed from specified 3rd party PCs</td>
</tr>
</tbody>
</table>

**VIII. Conclusion**

This submission includes software (NPSA) only. There are no technological changes to the hardware (NGS) in this submission. There are no changes to the intended use in this submission. There are no fundamental changes to the technology. Our performance testing demonstrates substantially equivalent performance of the NPSA as compared to the predicate.