Dear Mr. Ryan:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K170172

Device Name
UNiD Spine Analyzer

Indications for Use (Describe)
The UNiD Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons or service providers to perform generic, as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgement and experience are required to properly use the software.

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.

"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
PRARStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
MEDICREA INTERNATIONAL’S UNiD SPINE ANALYZER

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the UNiD Spine Analyzer.

1. **Submitter:**

MEDICREA INTERNATIONAL
5389 Route de Strasbourg - Vancia
69140 RILLIEUX LA PAPE
FR

Date Prepared: April 25, 2017

2. **Trade name:** UNiD Spine Analyzer

**Classification Name:**

Class II, Picture archiving and communications system (21 C.F.R. 892.2050)

**Classification and Regulation:**

LLZ: system, image processing, radiological

3. **Predicate or legally marketed devices which are substantially equivalent**

**Primary predicate:**

- SURGIMAP 2.0 (NEMARIS INC, K141669)

4. **Description of the device**

UNiD Spine Analyzer is a software solution developed for the medical community. It is intended to be used to view images and perform spine related measurements and plan surgical procedures. The planning of surgical procedures can be done either by MEDICREA as part of the service of designing patient specific implant (surgeons will have to validate the planning submitted by MEDICREA before the manufacturing of any implants) or by the surgeon himself. The image formats supported encompass the standard image formats (jpeg, png, gif). Measurements (generic, measuring and surgical tools) can be overlaid to each image. UNiD Spine Analyzer offers the ability to plan certain surgical procedures, such as osteotomies of the spine, and templating implants (screws, cages and rods). Patient
specific rods can be ordered to be manufactured by MEDICREA. UNiD Spine Analyzer is a web-based software.

5. Indications for Use

The UNiD Spine Analyzer is intended for assisting healthcare professionals in viewing and measuring images as well as planning orthopedic surgeries. The device allows surgeons or service providers to perform generic, as well as spine related measurements on images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

6. Substantial equivalence claimed to predicate devices

The table below compares the features and technological characteristics of UNiD Spine Analyzer to its predicate device:

**Table 1**: Comparison of features and technological characteristics of UNiD Spine Analyzer and its predicate

<table>
<thead>
<tr>
<th>Feature</th>
<th>UNiD Spine Analyzer</th>
<th>Surgimap 2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Computer</strong></td>
<td>PC Compatible</td>
<td>PC Compatible</td>
</tr>
<tr>
<td><strong>Operating System</strong></td>
<td>Windows + MAC</td>
<td>Windows + MAC</td>
</tr>
<tr>
<td><strong>Image Input</strong></td>
<td>Local</td>
<td>Local + PACS connectivity</td>
</tr>
<tr>
<td><strong>Runs on Server</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Osteotomy Module</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Generic measurements</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Spine measurements</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Pre-operative planning</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Custom implants</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Database</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Case sharing</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Human Intervention for interpretation and manipulation of images</strong></td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td><strong>Web content</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
7. Non-clinical test summary

Performance data for the UNiD Spine Analyzer consisted of verification and validation activities. Software verification and validation testing was 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 on Medical Devices”. Agency recommendations in the guidance entitled “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” was followed to validate the UNiD Spine Analyzer. The software for this device was considered to be of moderate level of concern.

For basic measurement testing (angles and distances), random lines and angles have been drawn and measured by two different tools: Surgimap, which is the claimed predicate device, and the subject device, and the two values have been compared. Several configurations and values were tested. The mean error and the standard deviation (for distances and angles) were calculated to establish substantial equivalence. Mean error obtained for distance was 0.23mm and standard deviation was 0.42mm. For angles, mean error obtained was 0.2° and standard deviation was 0.4°.

For surgical tools (wedge and cage), sets of images were created with the wedge(s) or cage(s) to apply. For each image, the tool(s) was(were) applied, and the obtained images (with UNiD Spine Analyzer and with Surgimap) were superimposed to confirm that the measurements that moved because of the wedge(s) are at the same place using the two different software devices. Possible deviation (angle) was measured. Mean error and standard deviation was calculated to establish substantial equivalence. Mean error obtained for wedge tool was 0.25° and standard deviation was 0.44°. For cages, mean error obtained was 0.4° and standard deviation was 0.5°.

All performance testing demonstrates that the subject device is substantially equivalent to the predicate device.

8. Conclusion

The UNiD Spine Analyzer is substantially equivalent to the legally marketed predicate device as demonstrate by the completed performance testing.