DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medicrea International   May 24, 2017
℅ Mr. David Ryan
VP Product Development and Marketing
5389 route de Strasbourg – Vancia
69140 Rillieux-la-Pape
FRANCE

Re: K170172
     Trade/Device Name: UNiD Spine Analyzer
     Regulation Number: 21 CFR 892.2050
     Regulation Name: Picture archiving and communications system
     Regulatory Class: II
     Product Code: LLZ
     Dated: April 25, 2017
     Received: April 27, 2017

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,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

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.

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:	Contact Person:
	David RYAN
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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

Feature	UNiD Spine Analyzer	Surgimap 2.0
Computer	PC Compatible	PC Compatible
Operating System	Windows + MAC	Windows + MAC
Image Input	Local	Local + PACS connectivity
Runs on Server	Yes	No
Osteotomy Module	Yes	Yes
Generic measurements	Yes	Yes
Spine measurements	Yes	Yes
Pre-operative planning	Yes	Yes
Custom implants	Yes	Yes
Database	No	Yes
Case sharing	No	Yes
Human Intervention for interpretation and manipulation of images	Required	Required
Web content	Yes	Yes

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.