April 25, 2023

CTL Medical Corporation
Barry E. Sands
President and Founder
RQMIS Inc.
110 Haverhill Road
Suite 524
Amesbury, Massachusetts 01913

Re: K220513
Trade/Device Name: NITRO Interbody Fusion Cage System Family
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX, OVE
Dated: April 12, 2023
Received: April 12, 2023

Dear Mr. Sands:

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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220513

Device Name
NITRO Interbody Fusion Cage System Family

Indications for Use *(Describe)*
"CERVICAL" NITRO Interbody Fusion Cage System Family (i.e., the MATISSE NITRO Anterior Cervical Interbody Fusion Cage System and the MONET NITRO Anterior Cervical Interbody Fusion Cage System) are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level or two contiguous levels.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Cervical NITRO Interbody Fusion Cage System Family are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach from the C2-C3 disc space to C7-T1 disc space using autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Cervical NITRO Interbody Fusion Cage System Family are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

When the MONET Anterior Cervical Interbody Fusion Cage System is used with the Supplementary Fixation Plate assembly, the plate-spacer assembly is a stand-alone device intended for use at one disc level or two contiguous levels of the cervical spine (from the C2-C3 disc space to C7-T1 disc space).

"LUMBAR" NITRO Interbody Fusion Cage System Family (i.e.; the MONDRIAN NITRO Lumbar Interbody Fusion Cage System consisting of ALIF/OLIF, DLIF, PLIF, and TLIF) are indicated for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s).

Lumbar NITRO Interbody Fusion Cage System Family are intended to be used with supplemental spinal fixation systems. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

Lumbar NITRO Interbody Fusion Cage System Family with hyperlordotic cage offerings (>20°) require the use of anterior fixation.

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.

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510(k) SUMMARY

CTL Medical's NITRO Interbody Fusion Cage System Family (Cervical and Lumbar)

I. SUBMITTER'S ADDRESS, TELEPHONE NUMBER, CONTACT PERSON

CTL Medical Corporation
Sean Suh
4550 Excel Parkway, Suite 300
Addison, TX 75001
Phone: (214) 545-5820
Email: ssuh@ctlamedica.com

Contact Person:

Barry E. Sands
RQMIS Inc.
110 Haverhill Road, Suite 524
Amesbury, MA 01913
Phone: (978) 358-7307
Email: barrysands@rqmis.com
Facsimile: (978) 477-0206

Date Prepared: April 11, 2023

II. SUBJECT DEVICE

Trade/proprietary name of device:	**NITRO Interbody Fusion Cage System Family (Cervical and Lumbar)**
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Cervical and Lumbar
Regulation Number:	21 C.F.R. §888.3080
Classification:	Class II
Product Code(s)	ODP, MAX, OVE

III. PREDICATE DEVICES

Primary Predicate:

- VALEO Spacer System; VALEO II Interbody Fusion Device System (K143518), (K161405) (primary predicate)

Additional Predicates:

- MATISSE Anterior Cervical Interbody Cage System (K121569, K162682, K172212)
- MONET Anterior Cervical Interbody Fusion Cage System (K172788)
- MONET Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate (K182151), and
- MONDRIAN Lumbar Interbody Fusion Cage System (K192863)

IV. DEVICE DESCRIPTION

The NITRO Interbody Fusion Cage System Family (Cervical and Lumbar) cages offer a complete line of interbody cages for the cervical levels C2-C7 and the lumbar levels L2-S1 to be used with supplemental fixation and bone graft material. The cages are made of silicon nitride material and are available in a variety of widths, lengths, heights, and lordotic angles, (parallel angles to accommodate varying degrees of lordosis and varying patient anatomy). The NITRO Interbody Fusion Cage System Family consists of hollow intervertebral spacers with an axial void designed to hold bone graft material. The bone graft is packed into and around the cage to further facilitate fusion.

Each system includes a complete set of instruments to implant the devices properly. The NITRO Interbody Fusion Cage System Family consists of following systems:

- MATISSE NITRO Anterior Cervical Interbody Fusion Cage (ACIF) System.
- MONET NITRO Anterior Cervical Interbody Fusion Cage (ACIF) System with Supplemental fixation.
- MONDRIAN NITRO Lumbar Interbody Fusion Cage System:
    - MONDRIAN NITRO ALIF/OLIF Cage System
    - MONDRIAN NITRO DLIF Cage System
    - MONDRIAN NITRO PLIF Cage System
    - MONDRIAN NITRO TLIF Cage System

The NITRO Interbody Fusion Cage System Family includes implants and instruments. The subject system uses the same instruments and fundamental technology as do their functional counterparts in CTL Medical's already cleared MATISSE, MONET, and MONDRIAN surgical instruments. As with the predicates, the subject device is

implanted using a combination of device-specific and universal instruments manufactured from stainless steel materials that conform to ASTM F899.

Intended Use/Indications for Use: CERVICAL

"CERVICAL" NITRO Interbody Fusion Cage System Family (i.e., the MATISSE NITRO Anterior Cervical Interbody Fusion Cage System and the MONET NITRO Anterior Cervical Interbody Fusion Cage System) are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level or two contiguous levels.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Cervical NITRO Interbody Fusion Cage System Family are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach from the C2-C3 disc space to C7-T1 disc space using autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Cervical NITRO Interbody Fusion Cage System Family are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

When the MONET Anterior Cervical Interbody Fusion Cage System is used with the Supplementary Fixation Plate assembly, the plate-spacer assembly is a stand-alone device intended for use at one disc level or two contiguous levels of the cervical spine (from the C2-C3 disc space to C7-T1 disc space).

Intended Use/Indications for Use: LUMBAR

"LUMBAR" NITRO Interbody Fusion Cage System Family (i.e.; the MONDRIAN NITRO Lumbar Interbody Fusion Cage System consisting of ALIF/OLIF, DLIF, PLIF, and TLIF) are indicated for use with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s).

Lumbar NITRO Interbody Fusion Cage System Family are intended to be used with supplemental spinal fixation systems. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

Lumbar NITRO Interbody Fusion Cage System Family with hyperlordotic cage offerings (>20°) require the use of anterior fixation.

V. TECHNOLOGICAL CHARACTERISTICS

The NITRO Interbody Fusion Cage System Family is substantially equivalent to the following predicate devices: Primary predicate VALEO Spacer System; VALEO II Interbody Fusion Device System (K143518) and additional predicates MONET Anterior Cervical Interbody Fusion Cage System with Supplementary Fixation Plate (K182151), and MONDRIAN Lumbar Interbody Fusion Cage System (K192863).

The NITRO Interbody Fusion Cage System Family has identical intended use and indications, technological characteristics, and principles of operation as the primary and secondary predicates. Additionally, the company also used the additional predicate devices (MATISSE, MONDRIAN, and VALEO II devices above) to demonstrate that some technological characteristics of the subject device do not raise different questions of safety and effectiveness.

VI. PERFORMANCE DATA

The performance testing of the worst-case subject device MONET NITRO Cervical Cage was compared to the performance testing of the worst-case reference predicate cages (Cervical and Lumbar). Testing included Axial Static Compression, Shear Static Compression, Static Torsion, Axial Dynamic Compression, Subsidence, and Expulsion. Additionally, the Company also conducted Plate Pull-Off, Screw Push Out, and Pyrogenicity testing.

VII. CONCLUSION

The NITRO Interbody Fusion Cage System Family (Cervical and Lumbar) has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Thus, the subject device is substantially equivalent to the predicate device.

The technological differences between the subject device and the predicate do not raise new questions of safety and effectiveness. Any minor differences in technological characteristics have been tested and documented.