August 4, 2020

Linacol MUH DAN KIM CEV TEK MED ITH IHR SAN VE TIC
℅ Mehmet Ali Cengiz
Production Manager
Universiteler Mah. 1596. Cd. Safir Bloklari E Blok Kapi
No:6 Ofis No: 02/03
Ankara, 06800 Turkey

Re: K191670
Trade/Device Name: CureOs TCP
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: July 24, 2020
Received: July 27, 2020

Dear Mehmet Cengiz:

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,

Laura C. Rose, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191670

Device Name
CureOs TCP

Indications for Use *(Describe)*

CureOsTCP is indicated only for filling bone voids or defects that are not intrinsic to the stability of the bony structure. CureOs TCP is to be gently packed into bony voids or gaps of the skeletal system (such as the extremities, and the pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CureOs TCP is a bone graft substitute that resorbs and is replaced with bone during the healing process.

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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5. 510 (k) SUMMARY

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safely and effectiveness information is provided.

5.1. General Information

Submitter Name / Address	Linacol MUH. DAN. KIM. CEV. TEK. MED. ITH. IHR. SAN. VE TIC. Universiteler Mah. 1596. Cd. Safir Blokları E Blok Kapı No: 6 Ofis No: 02/03 06800 CANKAYA TURKEY
Date	08/04/2020
Contact Person	Mehmet Ali Cengiz malicengiz@linacolmedikal.com Phone: +90 312 299 2563

5.2. Device Name

510(k) Number	: K191670
Trade or Proprietary Name	: CureOs TCP
Common or Usual Name	: Bone Void Filler
Regulation Number	: 21 CFR 888.3045
Regulatory Class	: II
Product Code	: MQV

5.3. Predicate Devices

The subject device is substantially equivalent in safety and effectiveness to following legally marketed device (predicate) Kasios TCP (K042340).

5.4. Device Description

The CureOs TCP is a synthetic resorbable calcium phosphate bone void Filler. It is an osteoconductive material which provides a porous scaffold upon which bone formation can occur. The interconnected porosity ranges from 60 to 80% with a pore size range of 200 to 500pmn. The device is available in a variety of shapes and sizes.

5.5. Indication for use

CureOsTCP is indicated only for filling bone voids or defects that are not intrinsic to the stability of the bony structure. CureOs TCP is to be gently packed into bony voids or gaps of the skeletal system (such as the extremities, and the pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CureOs TCP is a bone graft substitute that resorbs and is replaced with bone during the healing process.

5.6. Summary of Technological Characteristics

CureOS TCP consists of moldable, biocompatible, resorbable calcium phosphate based material that can be applied directly to the intended sites. The polymer carrier used in CureOS is bioinert and biocompatible with host tissue and presents no new safety issues.

The intended use, and critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) of CureOs TCP are substantially equivalent to the predicate device, Kasios TCP (K042340).

5.7. Summary of Non-clinical Test

Critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) of CureOs TCP were compared with those of Kasios TCP (K042340). Chemistry was determined by Fourier Transformed Infrared Spectroscopy (FTIR) and Xray Diffraction (XRD) techniques. Crystallinity was determined by X-ray Diffraction. Physical form was determined by Scanning Electron Microscopy. Porosity was determined by Mercury Intrusion Porosimetry. Performance test results demonstrated that CureOs TCP has substantially equivalent critical specifications (chemistry, crystallinity, physical form, porosity, and solubility) as the predicate device Kasios TCP (K042340).

CureOs TCP biocompatibility testing was performed in accordance with the standards set forth in ISO 10993-1, Biological Evaluation of Medical Devices and the test results demonstrated that CureOs TCP met the requirements of the ISO standards.

CureOs TCP LAL (pyrogenicity) test was perfomed in accordance with the standards USP 35 NF 30 2012 (85), and European Pharmacopoeia 7th Edition Volume 1 and the test results demonstrated that CureOs TCP met the requirements of the related standard and no endotoxin has been observed when tested with 0,125 EU/ml sensivity.

CureOs TCP will be provided as a single use, sterile product. The radiation dose was be validated in accordance with ISO 11137-2006, Sterilization of Health Care Products - Radiation to Sterility Assurance Level (SAL). The results of risk management indicate that the identified hazards were acceptable and/or mitigated to an acceptable level with the residual risk evaluation deemed as acceptable per defined procedures.

5.8. Summary of Clinical Tests

CureOs TCp does not require clinical test.

5.9 Conclusion

The manufacturer compared the critical specifications - chemistry, crystallinity, physical form, porosity, dissolution/solubility of CureOs TCP with the predicate device. The results indicated that the device characteristics for CureOs Tcp were the same as those of the predicate device. Therefore, CureOs TCP bone void filler is substantially equivalent to the predicate device, Kasios TCP Bone Void Filler (K042340).