October 21, 2020

C4 Imaging LLC
Andrew Bright
President and CEO
196 West Ashland Street
Doylestown, Pennsylvania 18901

Re: K192771
Trade/Device Name: C4 Fiducial Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: September 26, 2019
Received: September 30, 2019

Dear Mr. Bright:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K192771

Device Name
C4 Fiducial Marker

Indications for Use *(Describe)*
The C4 Fiducial Marker is indicated to be implanted into the body in situations where the location of specific anatomy, normal or diseased, needs to be marked for a future medical procedure. The device can be visualized using MRI, CT or x-ray, and provides a reference from which other procedures can be guided.

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

[as required by section 807.92(c)]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

General Information

Submitted by:	C4 Imaging, LLC 196 West Ashland Street Suite 109 Doylestown, PA 18901 USA Phone: +1 (609) 933-5895 Email: abright@c4imaging.com Contact Person: Andrew Bright
Date Prepared:	October 20, 2019

Device Name

Trade Name:	C4 Fiducial Marker
Common Name(s):	Anatomical tissue marker

Classification

Regulation:	21 CFR §878.4300
Class:	Class II
Product Code:	NEU
Classification name:	Marker, Radiographic, Implantable

Predicate Devices

Mixed media marker	K102506	Cortex Manufacturing
BiomarC Fiducial Marker	K063193	Carbon Medical Technologies

Device Description

The C4 Fiducial Marker consists of a sealed polyether ether ketone (PEEK) polymer tube containing a solution of up to 1% cobalt chloride and up to 2% N-Acetylcysteine, The ratio of cobalt chloride to N-Acetylcysteine is 1:2. Zirconium oxide is sealed within the polymer shell of the device. The length of the polymer capsule is between 5.5 mm and 10.0 mm, and the diameter is 1.0 mm (+/- 0.2 mm).

Indication

The C4 Fiducial Marker is indicated to be implanted into the body in situations where the location of specific anatomy, normal or diseased, needs to be marked for a future medical procedure. The device can be visualized using MRI, CT or x-ray, and provides a reference from which other procedures can be guided.

Comparison to Predicate Devices

The indication and technological characteristics of the C4 Fiducial Marker are substantially equivalent to the Mixed Media Marker (Cortex Manufacturing – K102506) and the BiomarC Fiducial Marker (Carbon Medical Technologies – K063193). Like the Mixed Media Marker, the C4 Fiducial Marker is comprised of a sealed polyether ether ketone (PEEK) capsule that encloses an internal marker for MRI, CT and X-ray imaging. In both cases the PEEK capsule is the only patient contacting material. Like the BiomarC Fiducial, the C4 Fiducial Marker has a sealed biocompatible shell that encloses a zirconium oxide marker.

The C4 Fiducial Marker was also compared to a reference device, the C4 Imaging MRI Marker NS (K171487), which has similar technological characteristics. The C4 Fiducial Marker and the MRI Marker NS both comprise a PEEK shell enclosing a cobalt chloride N-acetyl cysteine solution.

A risk evaluation, based on a Failure Mode Effect Analysis (FEMA), determined that technological differences were not considered to have an impact on the safety or effectiveness of the C4 Fiducial Marker. Adoption evaluation of biocompatibility, MR compatibility, sterilization, structural integrity, packaging and shelf life data during the risk assessment confirmed the C4 Fiducial Marker is substantially equivalent to the predicate devices and reference device.

Performance Testing

The C4 Fiducial Marker was subject to structural and functional integrity testing involving negative and positive pressure, as well as axial and lateral load testing. These integrity tests were followed by MRI, CT and x-ray imaging demonstrating functional performance. Separate MRI, CT and x-ray imaging tests were performed in tissue equivalent phantoms. A biocompatibility (ISO 10993) assessment and endotoxin tests were performed on the device.

Conclusion

The C4 Fiducial Marker is substantially equivalent to the Mixed Media Marker (K102506) and to the BiomarC Fiducial Marker (K063193). There are no differences that would affect the substantial equivalence of the proposed device