DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 28, 2014

InFront Medical, LLC
Mr. John D. Kuczynski
President
1033 U.S. Highway 46 East, Suite A202
Clifton, New Jersey 07013

Re: K141443
Trade/Device Name: InFront Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 21, 2014
Received: June 2, 2014

Dear Mr. Kuczynski:

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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K141443

Device Name: InFront Lumbar Interbody Fusion System

Indications for Use:

The InFront Lumbar Interbody Fusion System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be use with autograft bone.

Prescription Use	AND / OR	Over-The-Counter Use
X		
(Per 21 CFR 801.109) Subpart D		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Prepared May 29, 2014

1. **Company:** InFront Medical, LLC
1033 US Highway 46 East
Suite A202
Clifton, NJ 07013 USA
Tel: (888) 515-2532
FAX: 888-292-4691

2. **Contact:** John Kuczynski
President
InFront Medical, LLC
1033 US Highway 46 East
Suite A202
Clifton, NJ 07013
Tel: 973-906-2891
FAX: 888-292-4691

3. **Proprietary Name:** InFront Lumbar Interbody Fusion System

4. **Classification Name:** Intervertebral Body Fusion Device (21 CFR 888.3080); Class II, Product Code MAX

5. **Product Description:**

The InFront Lumbar Interbody Fusion System consists of cages of various lengths, widths and heights, which can be inserted between two lumbar or lumbrosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The InFront Lumbar Interbody Fusion System is to be used with supplemental fixation. The leading edge consists of bullet nose. The cephalad/caudal opening is large to allow for bone through growth. In addition, there are 2 large holes on each side to facilitate bone and to aid in visualizing the fusion mass. The teeth are slanted away from the direction of insertion of the implant to minimize implant migration. The superior and inferior surfaces are convex to better fit the vertebral endplates.

The device is offered in 3 general configurations, specifically shaped for posterior, transforaminal or lateral surgical approaches. The posterior approach configuration is available in 508 possible sizes, with lengths from 22mm to 36mm, widths from 8mm to11mm, heights from 7mm to 16mm and lordosis angles of 0°, 4° and 8°. The transforaminal approach configuration is available in 720 possible sizes, with lengths from 22mm to 36mm, widths from 9mm to 12mm, heights from 7mm to 18mm and lordosis angles of 0°, 4° and 8°. The lateral approach configuration is available in 330 possible sizes, with lengths from 40mm to 60mm, widths from 18mm to 22mm, heights from 8mm to 18mm and lordosis angles of 0°, 4° and 8°.

The InFront Lumbar Interbody Fusion devices are made from PEEK (Polyetheretherketone) per ASTM F2026, with radiographic markers made from tantalum per ASTM F560.

6. Indications for Use:

The InFront Lumbar Interbody Fusion System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be use with autograft bone.

7. Summary of Technological Characteristics

The InFront Lumbar Interbody Fusion System consists of a series of PEEK lumbar cages. These cages are intended to be placed between two lumbar or a sacral and lumbar vertebrae using instruments provided. The proposed devices are the same as current interbody cages already on the market with the only difference being minor variations in the shape.

InFront has determined that the minor differences between the proposed interbody fusion cages and the predicate devices will not impact the safety or effectiveness of the interbody fusion cages for their intended use. Analysis has shown that the proposed lumbar cages are equivalent to the predicate lumbar cages.

8. Identification of Legally Marketed Predicate Device

Documentation was provided which demonstrates that the subject InFront Interbody Cage System is substantially equivalent to several predicate devices that are currently on the market in the US, including the following:

Sapphire Medical Group A-Wedge (K121693, December 27, 2012)
Vertebron Interbody Fusion System (K073502, March 24, 2008)
Synthes Opal and Oracle Spacer (K072791, December 26, 2007)
Stryker AVS PL Spacer (K050624, April 11, 2005)
Stryker AVS TL Spacer (K083661, February 27, 2009)
Synthes TPAL Spacer (K100089, May 13, 2010)
Stryker AVS ARIA Spacer (K101051 August 12, 2010)

9. Brief Discussion of Non-Clinical Tests Submitted

The subject InFront Lumbar Interbody Fusion System and the predicate cage systems are identical in their indications for use, performance specifications and fundamental technological characteristics. The subject cage system was tested as described in "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" with the following tests being performed:

- Static Compression – ASTM F2077-11
- Dynamic Compression – ASTM F2077-11
- Subsidence – ASTM F2267-04
- Expulsion - Per ASTM Draft F04.25.0202

10. Conclusions from Non-Clinical Tests

Based on the results of the testing and comparisons performed, InFront believes that the subject InFront Interbody Fusion System is substantially equivalent to the predicate systems it was compared to.