October 7, 2020

Flower Orthopedics Corporation
Amanda Pentecost, Ph.D.
RA/QA Engineer
Flower Orthopedics Corp.
3973 Delp Street
Memphis, Tennessee 38118

Re: K192949
Trade/Device Name: Flower Suture Anchor Set
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 10, 2020
Received: September 11, 2020

Dear Dr. Pentecost:

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,

for

Laura Rose, Ph.D.
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)*
K192949

Device Name
Flower Suture Anchor Set

Indications for Use *(Describe)*
The Flower Suture Anchor Set is intended to be used to aid arthroscopic and orthopedic reconstructive procedures needing soft tissue fixation, due to injury or degenerative disease.

The FlowerAnchor, 3.0mm is indicated for use in soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:

• Shoulder indications: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
• Wrist/hand indications: Scapholunate ligament reconstruction.
• Foot/Ankle indications: Tendon repair/reconstruction, hallux valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
• Elbow indications: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.
• Knee indications: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.

The FlowerAnchor, 5.0mm and FlowerAnchor, Knotless is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:

• Shoulder indications: Bankart repair, rotator cuff repair, SLAP lesion repair,capsule repair or capsulolabral reconstruction, acromio-clavicular separation,deltoid repair, biceps tenodesis.
• Wrist/hand indications: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.
• Foot/Ankle indications: Achilles tendon repair/reconstruction, hallux valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
• Elbow indications: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.
• Knee indications: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure.

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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K192949
510(k) Summary
Flower Suture Anchor Set

Submitter: Flower Orthopedics Corporation

100 Witmer Rd. Suite 280
Horsham PA, 19044

Phone: 215-394-8903
Facsimile: 215-394-8904

Contact Person: Amanda Pentecost, Ph.D.
Date Prepared: September 29, 2020

Name of Device:

Flower Suture Anchor Set

Trade Name: Flower Suture Anchor Set

Common Name: Suture Anchor

Classification: Fastener, Fixation, Nondegradable, Soft Tissue (Product Code: MBI), Class II, Orthopedic Review Panel, 21 C.F.R. 888.3040

Predicate Devices:

Manufacturer	Trade Name	510K
Primary Predicate:		
RoG Sports Medicine Inc.	Rog Suture Anchor	K113299
Additional Predicates:		
Arthrex, Inc.	Arthrex 3.0mm SutureTak	K061863
RoG Sports Medicine Inc.	Rog Suture Anchor 5.5mm, 2.9mm	K110229
RoG Sports Medicine Inc.	Rog Knotless Suture Anchor	K110230
RoG Sports Medicine Inc.	Rog Suture Anchor, Rog Knotless Suture Anchor	K111590
RoG Sports Medicine Inc.	Modified Rog Suture Anchor	K112991

Device Description

The Flower Suture Anchor Set consists of FlowerAnchor, 3.0mm, FlowerAnchor, 5.0mm, and FlowerAnchor, Knotless with lengths of 10mm and 17mm, respectively. The anchors are screw-like in shape and made of PEEK. The anchors are threaded with ultra-high molecular weight polyethylene (UHMWPE) non-absorbable sutures. The 3.0mm and 5.0mm anchors, USP Size 0 and Size 2 sutures, and inserters and the Knotless anchor and inserter are supplied as a single assembly, sterilized by ethylene-oxide, nonpyrogenic, and ready-for-surgery.

Accessories of Taps and Drill Bit Kits are supplied sterile by means of gamma radiation with the Flower Suture Anchor Set.

Intended Use / Indications for Use

The Flower Suture Anchor Set is intended to be used to aid arthroscopic and orthopedic reconstructive procedures needing soft tissue fixation, due to injury or degenerative disease.

The FlowerAnchor, 3.0mm is indicated for use in soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:

- Shoulder indications: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis.
- Wrist/hand indications: Scapholunate ligament reconstruction.
- Foot/Ankle indications: Tendon repair/reconstruction, hallux valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
- Elbow indications: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction.
- Knee indications: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.

The FlowerAnchor, 5.0mm and FlowerAnchor, Knotless is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows:

- Shoulder indications: Bankart repair, rotator cuff repair, SLAP lesion repair,capsule repair or capsulolabral reconstruction, acromio-clavicular separation,deltoid repair, biceps tenodesis.
- Wrist/hand indications: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction.
- Foot/Ankle indications: Achilles tendon repair/reconstruction, hallux valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions.
- Elbow indications: Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair.
- Knee indications: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure.

Substantial Equivalence							
Device	**Subject Device Flower Suture Anchor Set**	**Primary Predicate Rog Suture Anchor**	Arthrex 3.0mm SutureTak	Rog Suture Anchor 5.5mm, 2.9mm	Rog Knotless Suture Anchor	Rog Suture Anchor, Rog Knotless Suture Anchor	Modified Rog Suture Anchor
510(k)#	**K192949**	**K113299**	K061863	K110229	K110230	K111590	K112991
Intended Use	Secure soft tissue to bone	Secure soft tissue to bone	Secure soft tissue to bone	Secure soft tissue to bone	Secure soft tissue to bone	Secure soft tissue to bone	Secure soft tissue to bone
Indications for Use	The FlowerAnchor, 5.0mm and FlowerAnchor, Knotless is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair,capsule repair or capsulolabral reconstruction, acromio-clavicular separation,deltoid repair, biceps tenodesis. **Wrist/hand indications:** Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction. **Foot/Ankle indications:** Achilles tendon repair/reconstruction	The RoGTM 5.5 mm Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications**: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction. **Foot/ankle indications:** Achilles tendon repair/reconstruction , hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot	The Arthrex Corkscrew Family of Suture Anchors has been previously cleared in 510(k) K003817, K003227, K043337, and K050358. These suture anchors are intended for fixation of suture(soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, elbow, and pelvis in, but not limited to, the following procedures: **Shoulder:** Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction. **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon	The RoG 5.5 mm Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows: **Shoulder indications**: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications**: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction. **Foot/Ankle indications:** Achilles tendon repair/reconstructi on, hallax valgus reconstruction, lateral	The RoG 5.5mm Knotless Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foottankle and knee. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis- **Wrist/Hand indications:** Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction. **Foot/Ankle indications:** Achilles tendon repair/reconstruction , hallax valgus reconstruction, lateral stabilization, medial stabilization,	The RoG 5.5 mm Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows: **Shoulder indications**: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications**: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction. **Foot/Ankle indications:** Achilles tendon repair/reconstruction , hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot	The RoG 5.5 mm Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows: **Shoulder indications**: Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications**: Ulnar/Radial collateral ligament reconstruction, scapholunate ligament reconstruction. **Foot/Ankle indications:** Achilles tendon repair/reconstruction , hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot

	, hallux valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure. The FlowerAnchor, 3.0mm is indicated for use in soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction,	reconstructions. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure. The RoGTM 2.9mm Suture Anchor is indicated for use in soft tissue reattachment procedures. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications:** Scapholunate ligament reconstruction. **Elbow indications:** Biceps tendon reconstruction, ulnar	Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament [Tendon Repair], Bunionectomy. **Knee:** Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Iliotibial Band Tenodesis. **Hand/Wrist:** Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction. **Elbow:** Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair. Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility of intrinsic sphincter	stabilization, medial stabilization, mid- and forefoot reconstructions. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. Iliotibial band tenodesis, joint capsule closure. The RoG 2.9mm Suture Anchor is indicated for use in soft tissue reattachment procedures. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps	mid- and forefoot reconstructions. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. Iliotibial band tenodesis, joint capsule closure.	reconstructions. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. Iliotibial band tenodesis, joint capsule closure. The RoG 2.9mm Suture Anchor is indicated for use in soft tissue reattachment procedures. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications:** Scapholunate ligament reconstruction. **Elbow indications:** Biceps tendon	reconstructions. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. Iliotibial band tenodesis, joint capsule closure. The RoG 2.9mm Suture Anchor is indicated for use in soft tissue reattachment procedures. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications:** Scapholunate ligament reconstruction. **Elbow indications:** Biceps tendon reconstruction, ulnar

	acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications:** Scapholunate ligament reconstruction. **Foot/Ankle indications:** Tendon repair/reconstruction, hallux valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.	or radial collateral ligament reconstruction. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure, extracapsular repair, vastus medialis obliquus (VMO) muscle advancement. The RoGTM 5.5 mm Knotless Suture Anchor is indicated for soft tissue reattachment procedures in the shoulder, elbow, wrist/hand, foot/ankle and knee. Specific indications are as follows: **Shoulder indications:** Bankart repair, rotator cuff repair, SLAP lesion repair, capsule repair or capsulolabral reconstruction, acromio-clavicular separation, deltoid repair, biceps tenodesis. **Wrist/hand indications:** Ulnar/Radial collateral ligament reconstruction, scapholunate	deficiency. Hip: Capsular repair, acetabular labral repair.	tenodesis. **Wrist/hand indications:** Scapholunate ligament reconstruction. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction. **Knee indications**: Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. Iliotibial band tenodesis, joint capsule closure. Extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.		reconstruction, ulnar or radial collateral ligament reconstruction. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. Iliotibial band tenodesis, joint capsule closure. Extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.	or radial collateral ligament reconstruction. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair. Iliotibial band tenodesis, joint capsule closure. Extracapsular repair, vastus medialis obliquus (VMO) muscle advancement.

		ligament reconstruction. **Foot/ankle indications:** Achilles tendon repair/reconstruction , hallax valgus reconstruction, lateral stabilization, medial stabilization, mid- and forefoot reconstructions. **Elbow indications:** Biceps tendon reconstruction, ulnar or radial collateral ligament reconstruction, lateral epicondylitis repair. **Knee indications:** Lateral collateral ligament repair, medial collateral ligament repair, posterior oblique ligament repair, patellar ligament/tendon repair, iliotibial band tenodesis, joint capsule closure.					
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue	Screw, Fixation, Bone	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue
Product Code	MBI	MBI	HWC (JDR, MAI, MBI)	MBI	MBI	MBI	MBI
Material	PEEK	PEEK	PEEK	PEEK	PEEK	PEEK	PEEK
Sizes	3.0mm, 5.0mm	5.5mm, 2.9mm	3.0mm	5.5mm, 2.9mm	5.5mm	5.5mm, 2.9mm	5.5mm, 2.9mm

Comparison of Technological Characteristics

Soft tissue reattachment aid using PEEK anchors and non-absorbable suture is the technological principle for both the subject and predicate devices. It is based on the use of one or more PEEK anchors with non-absorbable sutures. At a high level, the subject and predicate devices have the same indication for use and are made from the same materials. The suture is from the same supplier as the primary predicate. Anchors are both made from PEEK. Additionally, both the subject and predicate devices are provided sterile.

There are several technological differences between the subject and predicate devices. The primary predicate device offers a 2.9mm and 5.5mm diameter anchor while Flower Orthopedics Suture Anchor Set offers a 3.0mm and 5.0mm diameter anchor. Thus, the proposed diameters for the Flower Orthopedics Suture Anchor Set is within the range of the predicate devices. Although there are minor differences in dimensions and design, testing of the subject device establishes equivalent mechanical strength of the subject device as compared to the predicate device. The primary predicate device offers a single strand of USP size 2 suture with their 2.9mm anchor while the FlowerAnchor 3.0mm offers two strands of USP size 0 sutures. The sutures have been previously cleared.

Performance Data

The Flower Suture Anchor Set was tested (worse case) in accordance with FDA's Draft Guidance Document for Testing Bone Anchor Devices. Testing consisted of Insertion, Pull out, and Fatigue in comparison to the predicate devices. The subject device was found to be equivalent to the predicate devices in such performance. Cytotoxicity testing was also separately performed on both the patient-contacting and non-patient-contacting components

Additionally, the Flower Suture Anchor Set was evaluated according to the following standards:

- USP 41-NF36:2018 <861>, Sutures – Diameter
- USP 41-NF36:2018 <871>, Sutures – Needle Attachment
- USP 41-NF36:2018 <881>, Tensile Strength
- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;
- ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-7, Ethylene oxide sterilization residuals
- ISO 11135-1, Ethylene Oxide Sterilization
- ISO 11137, Radiation Sterilization
- ANSI/AAMI ST72:2011/ (R)2016, Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing

In all instances, the Flower Suture Anchor Set functioned as intended and test results demonstrated substantial equivalence with the cited predicate devices.

Conclusions

The Flower Suture Anchor Set is as safe and effective as the identified predicate devices**.** The subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in the device configuration being packaged with additional sutures and inserters raise no new issues of safety or effectiveness Performance data demonstrate that the subject devices are as safe and effective as the predicate devices. Thus, the Flower Suture Anchor Set is substantially equivalent.