

DE NOVO CLASSIFICATION REQUEST FOR MISHA™ KNEE SYSTEM

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Medial knee implanted shock absorber. A medial knee implanted shock absorber is a device implanted outside of the knee capsule extending from the distal femur to the proximal tibia. It is intended to reduce loads on the intra-articular medial joint surface to improve symptoms of osteoarthritis. The device employs a shock absorbing mechanical system and is biomechanically stabilized by plates and screws. The device is not intended to span the lateral knee.

NEW REGULATION NUMBER: 21 CFR 888.3610

CLASSIFICATION: Class II

PRODUCT CODE: QVV

BACKGROUND

DEVICE NAME: MISHA™ Knee System

SUBMISSION NUMBER: DEN220033

DATE DE NOVO RECEIVED: July 6, 2022

SPONSOR INFORMATION:

Moximed, Inc.
46602 Landing Parkway
Fremont, California 94539

INDICATIONS FOR USE

The MISHA™ Knee System is indicated as follows:

The MISHA™ Knee System is indicated for patients with medial compartment knee osteoarthritis that have failed to find relief in surgical and/or non-surgical treatment modalities and are still experiencing pain that interferes with activities of daily living and are also unwilling to undergo or ineligible for total knee replacement due to age or absence of advanced osteoarthritis.

LIMITATIONS

The sale, distribution, and use of the MISHA™ Knee System are restricted to prescription use in accordance with 21 CFR 801.109.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

Implant Description

The MISHA™ Knee System (**Figure 1**) is a prescription use, extra-capsular knee implant device that is comprised of a tibial base subassembly, femoral base subassembly, absorber subassembly, piston subassembly and locking screws. The tibial base subassembly, femoral base subassembly, piston subassembly and absorber subassembly are provided pre-assembled, and the implant is fixed with locking screws to the medial cortices of the distal femur and proximal tibia to share the loads with the knee joint. The articulating ball-and-sockets allow the implant to accommodate the natural motions of the knee. The implant bases and locking screws are made of titanium alloy and the sockets are CoCrMo alloy. The compressive component of the absorber is made of polycarbonate urethane. The femoral balls, tibial balls, and the internal lining of the absorber are made of carbon-fiber-reinforced polyetheretherketone (CFR-PEEK). The implant comes in two sizes (small and large) and right or left configurations.



Figure 1: MISHA™ Knee System Implant

Instrument Description

The instruments for the MISHA™ Knee System are used to facilitate targeting, trialing, and fixation of the implant. The instrumentation includes a Fixation Kit, Torque Limiting Driver, and Targeting and Trialing Kits. The Targeting and Trialing kits are intended to support sizing and proper implant selection.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The MISHA™ Knee System is manufactured from the following patient contacting materials:

Table 1: Manufactured Materials of Patient-Contacting Device Components

Description	Material	Direct Patient Contact	Contact Duration
Knee System Implant	Cobalt Chromium per ASTM F1537; Ti6Al4V ELI per ASTM F136; CFR-PEEK, 80A PCU; 75D PCU	Yes	Permanent (>30 d)
Screws	Ti6Al4V ELI per ASTM F136	Yes	Permanent (>30 d)
Patient-contacting Instruments	Medical Grade Stainless Steel, Polycarbonate, and Silicone	Yes	Limited (≤ 24 h)

Biocompatibility evaluation has been completed according to 2020 FDA Guidance, Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.”

For the permanent implant, **Table 2** shows the biocompatibility testing performed and the results, which were acceptable for a permanent implant in contact with bone/tissue:

Table 2: Implant Biocompatibility Testing Performed

Test Description	Result
Cytotoxicity (per ISO 10993-5 (Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity))	Non-cytotoxic
Irritation (per ISO 10993-10 (Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization))	Non-irritant
Sensitization (per ISO 10993-10 (Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization))	Non-sensitizing
Implantation Effects (per ISO 10993-6 (Biological evaluation of medical devices — Part 6: Tests for local effects after implantation))	Null to minimal reactivity
Material Mediated Pyrogenicity (per ISO 10993-11 (Biological evaluation of medical devices — Part 11: Tests for systemic toxicity))	Non-pyrogenic

Acute/Subacute/Subchronic/Chronic Systemic Toxicity, Genotoxicity and Carcinogenicity (addressed through chemical characterization and toxicological risk assessment per ISO 10993-18 (Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process)/ISO 10993-17 (Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances)	Non-systemically toxic/genotoxic/carcinogenic
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A 26-week combined implantation and systemic toxicity rabbit study was conducted per ISO 10993-11:2017 in combination with assessment of local implantation effects per ISO 10993-6:2016. The test articles did not produce local or systemic toxicological effects.

For the reusable instruments, **Table 3** shows the biocompatibility testing performed and the results, which were acceptable for instruments in limited contact with bone/tissue:

Table 3: Instrument Biocompatibility Testing Performed

Test Description	Result
Cytotoxicity (per ISO 10993-5 (Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity))	Non-cytotoxic
Irritation (per ISO 10993-10 (Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization))	Non-irritant
Sensitization (ISO 10993-10 (Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization))	Non-sensitizing
Acute Systemic Toxicity (per ISO 10993-11 (Biological evaluation of medical devices — Part 11: Tests for systemic toxicity))	Non-toxic

STERILITY/PACKAGING AND SHELF-LIFE/PYROGENICITY

Sterility:

The MISHA™ Knee System is a single-use device provided clean and sterile to the user. Gamma Sterilization of the device has been validated to provide a Sterility Assurance Level (SAL) of 10^{-6} based on the VDMax²⁵ method as recommended by FDA Recognized Consensus Standard series ANSI/AAMI/ISO 11137-1 (“Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices”)/-2 (“Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose”).

Packaging and Shelf-Life:

The MISHA™ Knee System comes in three different packaging configurations. Each configuration includes an inner pouch, an outer pouch, and a protective carton. The material of the packaging is outlined in **Table 4**. The implants, screws and trials all share the “Small” configuration. The Targeting Kit and Fixation Kits share the “Large” configuration. In addition, the Targeting and Fixation Kits are packaged on a mounting card. The configuration of the Torque Limiting Driver is the same inner and outer pouch as the Targeting and Fixation kit with a protective carton of slightly different dimensions.

Table 4: Materials of Construction of Packaging System Components

Inner and Outer Pouches	Protective Cartons	Mounting Cards
(b)(4)		

Non-clinical performance testing of the implant was used to assess the shelf-life of the device. The testing confirmed a 5-year shelf-life.

Pyrogenicity:

Bacterial endotoxins testing (BET) was performed to determine whether the MISHA™ Knee System met pyrogen limit specifications. All tested devices passed with a reported value of ≤ 1 EU/device, meeting the recommended endotoxin limits per ANSI/AAMI ST72:2011 (“Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing”).

MAGNETIC RESONANCE (MR) COMPATIBILITY

To support MR conditional labeling for the MISHA™ Knee System, the following MR testing was conducted to evaluate device safety and compatibility:

- Magnetically Induced Displacement Force per ASTM F2052-15, “Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment”;
- Magnetically Induced Torque per ASTM F2213-11, “Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment”;
- Radiofrequency Induced Heating per ASTM F2182-11a, “Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging”; and

- Imaging Artifacts per ASTM F2119-07 (Reapproved 2013), “Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants”

In magnetic field interaction tests, the MISHA™ Knee System implant showed a translation deflection angle of (b)(4), the maximum spatial gradient was (b)(4) and no torque. In image artifact testing, the maximum image artifact was measured for both spin echo and gradient echo pulse sequences in a 3.0 T MR scanner, and the maximum artifact size caused by the device extends approximately 37 mm from the implant when imaged with a gradient echo pulse sequence. In MRI-related heating testing, test results and in vivo modeling show that, the maximum temperature rise after 60 minutes continuous exposure is less than 6°C under the condition of the whole-body specific absorption rate (SAR) at 2 W/kg.

PERFORMANCE TESTING – BENCH

A summary of non-clinical mechanical performance evaluations is provided in **Table 5:**

Table 5: Summary of Non-clinical Mechanical Performance Evaluations

Test	Purpose	Method	Performance Criteria	Results
Absorber Unloading Capacity	Demonstrate the minimum compressive resistance force produced by the absorber at its implanted length.	(b)(4)	Demonstrate the minimum compressive resistance force produced by the absorber at its implanted length is $\geq$ 15 lbs.	All specimens exceeded the performance criteria.
Durability, Wear, and Corrosion Resistance	Demonstrate the implant functionality, wear rate and corrosion resistance in a simulated in vivo environment.		Demonstrate the mean polymeric and metallic wear rate are $\leq$ 6.1 and $\leq$ 0.004 mm³ per one million cycles, respectively. Demonstrate implant materials (including	The mean polymeric wear rate was 0.248 mm³ per one million cycles. The mean metallic wear rate was 0.004 mm³ per one million cycles.

Test	Purpose	Method	Performance Criteria	Results
		(b)(4)	markings) are corrosion resistant in simulated in vivo environments. Demonstrate the implant functionality can be maintained for ≥ 10 million simulated gait cycles at its implanted length. Functionality is defined as: (1) fixation of the bases on the bones is maintained, (2) the device carries load during low knee flexion angles representative of the stance phase of gait, and (3) device components remain contiguous and mobile relative to one another throughout knee motion.	There was no evidence of corrosion after immersion in the simulated in vivo environment. All test articles remained functional throughout testing (10.3 million cycles).
Static Strength	Demonstrate the implant will not fracture or break when subjected to clinically relevant loads.		Demonstrate the implant will not fracture or break when subjected to a static compressive load up to 60 lbs.	All articles survived a static compressive load of 65 lbs. without any signs of permanent deformation or damage of the structural components.

SUMMARY OF CLINICAL INFORMATION

Study Design

The sponsor conducted a prospective, multicenter clinical study comparing the Calypso Knee System (rebranded for this De Novo request) to the cohort of subjects treated with High Tibial Osteotomy (HTO) from a non-randomized trial (“GOAL” study-historical data from the Atlas IDE study). The Calypso Clinical Study was submitted to demonstrate the system’s safety and effectiveness. Propensity Score (PS) methodology was employed to account for potential selection bias in the non-randomized comparison of the two groups and resulting in a PS Analysis set of 81 Calypso subjects and 81 Control (HTO) subjects in data through 24 months post-treatment. Clinical and radiographic follow-up visits occurred at 6 weeks, 3, 6, 12, 18 (N/A for HTO), and 24 months post-treatment. The Control (HTO) group completed follow-up visit at 24-months and the Calypso Knee group will continue to be followed through 5 years post-treatment.

Subject Demographics

The study population included male or female subjects aged 25 to 65 years for the Calypso Knee group and 25 to 80 years for the Control (HTO) group, with a diagnosis of medial knee osteoarthritis and knee pain with an overall Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score ≥ 40 (scale 0-100), who have failed to improve after at least six months of conservative medical treatment.

A total of eighty-one (81) Calypso subjects and ninety-two (92) Control (HTO) subjects were enrolled. After PS matching, eight-one (81) Control (HTO) subjects were included in the study analysis. **Table 6** presents a summary of the baseline characteristics for the Calypso Knee group and Control (HTO) group:

Table 6: Patient Baseline Characteristics

Measure	Calypso	Control (HTO)
N	81	81
Age, years	51.2 $\pm$ 7.71	52.5 $\pm$ 7.58
BMI, kg/m ²	28.4 $\pm$ 3.44	29.3 $\pm$ 4.36
Duration (months) of OA symptoms	52.8 $\pm$ 54.33	35.3 $\pm$ 50.69
KL Grade	2.5 $\pm$ 0.88	2.8 $\pm$ 0.98
WOMAC Pain	60.4 $\pm$ 12.37	52.9 $\pm$ 13.10
WOMAC Function	59.9 $\pm$ 15.93	48.4 $\pm$ 13.78
Debridement	14.8%	13.6%
Microfracture	7.41%	11.1%
Sex = Male %	60.49%	65.43%
Failed non-operative treatment at/before Month 6 = Yes	100%	100%
Tourniquet Used	82.7%	75.3%
White	98.8%	100%
Non-Hispanic	96.3%	98%

The age and BMI of the Calypso Knee group and Control (HTO) group are similar. The percentage of male subjects for the Calypso Knee group was about 5% lower compared to the Control (HTO) group and on average the Calypso Knee group had OA symptoms for 17.5 months longer compared to the Control (HTO) group. Despite the difference of the duration of osteoarthritis (OA) symptoms, the Kellgren and Lawrence (KL) Grade was similar for both groups. The baseline characteristics for the Calypso Knee and Control (HTO) group are comparable.

Primary Endpoint

The primary endpoint is a Composite Clinical Success (CCS) demonstrating non-inferiority of the Calypso Knee System to HTO data from the GOAL study at 24 months post-treatment. A subject is considered a success at 24 months if all of the following components were met at 24 months:

- Clinically significant improvement of at least 20% from baseline on the WOMAC pain questions in the Knee Injury and Osteoarthritis Outcome Score (KOOS) Knee questionnaire with a change of ≥ 10 points
- Clinically significant improvement of at least 20% from baseline on the WOMAC function questions in the KOOS Knee questionnaire with a change of ≥ 10 points
- Freedom from the following device-related serious adverse events, or “Safety Endpoint Event” (SEE):
 - Deep infection requiring surgical intervention (Both arms)
 - Damage to adjacent neurovascular or ligament structures necessitating reconstruction (Both arms)
 - Non-union (HTO only)
- Maintenance of implant integrity as evaluated by radiographic assessment

In addition to the four components, the protocol noted that a subject would also be a failure if a conversion to arthroplasty occurs through 24-months.

The sponsor conducted analysis of the primary endpoint with multiple imputation based on average treatment effect in the treated (ATT) for Month 24 clinical composite score. Using multiple imputation to account for missing data, the success rate was 83.5% for the Calypso Knee group and 57.2% for the Control (HTO) group. Study success is based on *a priori* selected non-inferiority margin (δ) of -0.10. The success rate of the Calypso Knee group led the Control (HTO) group by 26.3% and the primary endpoint at 24 months was achieved in this study. Results are presented in **Table 7** for all study subjects.

Table 7: Primary Endpoint Success at Month 24 Post-Treatment

Outcome	Calypso			Control		
	N	n	%	N	n	%
Enrolled	81	81	100.0%	81	81	100.0%
No Endpoint Subsequent Surgical Intervention	81	80	98.8%	81	80	98.8%

Outcome	Calypso			Control		
	N	n	%	N	n	%
WOMAC Pain endpoint responder	72	69	95.8%	58	51	87.9%
WOMAC Function endpoint responder	72	66	91.7%	64	52	81.3%
No Safety Endpoint Event (CEC)	81	77	95.1%	81	76	93.8%
No Endpoint Implant Integrity Failure	81	80	98.8%	81	80	98.8%
Crude Observed	74	62	83.8%	63	41	65.1%
Completers	74	62	83.8%	63	34.3	54.4%
Multiple Imputation (MI)	81	67.6	83.5%	81	46.4	57.2%

A tipping point analysis was conducted to analyze the sensitivity of missing data. Compared to the multiple imputation model, the tipping analysis does not require the same statistical assumptions as it analyzes every possible combination of the missing data. The results from the tipping analysis indicate that the non-inferiority study conclusion is robust and not impacted by the missing data.

Secondary Endpoints

The sponsor assessed the following five secondary endpoints to evaluate the superiority of the Calypso Knee System to the Control (HTO):

- Time to full weight bearing
- Percent change from baseline to 3-months on the WOMAC pain in the KOOS Knee Survey
- Percent change from baseline to 3-months on the WOMAC function in the KOOS Knee Survey
- Percent change from baseline to 24-months on the WOMAC pain in the KOOS Knee Survey
- Percent change from baseline to 24-months on the WOMAC function in the KOOS Knee Survey

The results for the secondary endpoint are outlined in **Table 8** below:

Outcome	Calypso			Control		
	N	Mean	SD	N	Mean	SD
Time (days) to Full Weight Bearing	81	13.4	10.12	77	58.0	39.91
WOMAC Pain % Change from Baseline at Month 3	81	-55.5%	29.3%	72	-33.4%	35.8%
WOMAC Pain % Change from Baseline at Month 24	72	-76.0%	28.2%	58	-72.5%	33.0%
WOMAC Function % Change from Baseline at Month 3	81	-52.2%	32.0%	75	-24.3%	37.0%
WOMAC Function % Change from Baseline at Month 24	72	-73.9%	29.6%	64	-67.1%	35.8%

The results from the study supported superiority of the Calypso Knee group compared to the Control (HTO) group in four of the five secondary endpoints. The one endpoint that the data did not support superiority for the Calypso Knee group was the WOMAC Pain % change from Baseline at Month 24.

Safety Analysis

There were no Unanticipated Adverse Device Effects as determined by the independent medical monitor for both the Calypso Knee group and Control (HTO) group. All device- and procedure-related serious adverse events (SAEs) were considered expected complications. There were 11 removals (11/81, 13.58%) and 3 reoperations (3/81, 3.70%) for the Calypso Knee group and 61 removals (61/81, 75.31%), 1 revision (1/81, 1.23%), and 7 reoperations (7/81, 8.64%) for the Control (HTO) group. Note that the HTO plate can be electively removed after completing bone consolidation.

SAEs for the Calypso Knee group included 4 deep incisional surgical site infection (4/81, 4.94%) and 4 due to pain (4/81, 4.94%). Additional SAEs include nerve injury to a nerve resulting in motor or sensory symptoms, scar formation, discomfort, and cellulitis.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling consists of the following: device description, indications for use, instructions for use including surgical steps (e.g., device selection and placement), principles of device operation, identification of device materials, contraindications, warnings, precautions, a list of potential adverse effects, and summary of the clinical data. Furthermore, the sterile packaging includes a shelf-life for the device. The labeling meets the requirements of 21 CFR 801.109 for prescription devices.

TRAINING

The surgical technique program consisted of slides that walk the surgeon through each step of the procedure to implant the MISHA™ Knee System. The surgical technique training also provides insight on proper patient selection, surgical procedures, selection of appropriate implant size, instrumentation for implantation, indications for use of the device, contraindications, warnings, and precautions. A trained representative may be present to support surgical procedures.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the medial knee implanted shock absorber and the measures necessary to mitigate these risks.

Risks to Health	Mitigation Measures
Implant failure to improve osteoarthritis symptoms, including pain and discomfort	Clinical data Non-clinical performance testing Training
Pain and discomfort due to implant	Clinical data Training
Loss of implant integrity leading to loss of fixation and reoperation	Clinical data Non-clinical performance testing
Ligament or nerve injury resulting in motor and/or sensory damage	Clinical data Training
Scar formation	Clinical data Training
Infection	Sterilization validation Reprocessing validation Shelf-life testing Pyrogenicity testing Labeling
Adverse tissue reaction due to • Device materials • Fretting and corrosion • Wear particulates	Biocompatibility evaluation Non-clinical performance testing

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the medial knee implanted shock absorber is subject to the following special controls:

- (1) Clinical data must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
 - (i) Evaluation of improvement of knee function and reduction of osteoarthritis symptoms, including pain and function; and
 - (ii) Evaluation of relevant adverse events.
- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
 - (i) Evaluation of the mechanical function and durability of the implant (including evaluation of absorber unloading capacity, fretting and corrosion, static strength, wear analysis, and fatigue testing); and
 - (ii) Evaluation of worst-case device range of motion.

- (3) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (4) Performance data must support the sterility and pyrogenicity of the device components intended to be sterile.
- (5) Performance data must validate the reprocessing instructions for the reusable components of the device.
- (6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf-life.
- (7) A training program must be included so that upon completion of the training program, the user can safely and successfully implant the device.
- (8) Labeling must include the following:
 - (i) Validated methods and instructions for reprocessing of any reusable components; and
 - (ii) A shelf-life.

BENEFIT-RISK DETERMINATION

BENEFITS:

- 1) The clinical study demonstrates the MISHA™ Knee System leads to clinically meaningful improvements in knee function and symptoms (e.g., reduction in pain) that are maintained over time to at least 24 months;
- 2) Performance has been demonstrated to be non-inferior to High Tibial Osteotomy (HTO);
- 3) The MISHA™ Knee System secondary endpoint results (Return to Full Weight Bearing, Improved WOMAC Pain and Function Scores from baseline at 3 months, Improved WOMAC Function Scores from baseline at 24 months) support clinically meaningful, patient-valued benefits at a magnitude similar to, or numerically greater than, those observed with the Control HTO;
- 4) The MISHA™ Knee System does not require any bone cutting and maintains the natural joint surface compared to the Control HTO;
- 5) Preserves the knee joint for future surgeries compared to the Control HTO.

RISKS:

- 1) Adverse events of the index knee including pain, discomfort, unanticipated adverse device effects, subsequent surgical interventions, loosening and migration, and revision, including revision due to device wear, screw back out, or device failure;
- 2) Adverse tissue reactions due to device materials, fretting and corrosion, and wear particulates;
- 3) Infection;
- 4) Loss of implant integrity;
- 5) Ligament or nerve injury.

Based on the totality of the evidence, the MISHA™ Knee System demonstrated a reasonable assurance of safety and effectiveness for the device for its intended use/indications for use. While there is a low degree of uncertainty in this finding due to the missing data from the control group in the clinical study and removal rate for the MISHA™ Knee System, the risks are not greater than HTO. To address the concerns of the longer-term safety and benefits of the MISHA™ Knee System, the sponsor will be conducting a five (5) year 522 Postmarket

Surveillance Study. In addition, the MISHA™ Knee System demonstrated improvement on the WOMAC pain and function scores over the course of the clinical study. In conclusion, the benefits of using the MISHA™ Knee System for its intended use/indications for use outweigh the probable risks to health.

Patient Perspectives

Patient perspectives considered for the Misha Knee System during the review include:

- WOMAC Pain and Function Scores
- KSS Satisfaction Scores

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

“The MISHA™ Knee System is indicated for patients with medial compartment knee osteoarthritis that have failed to find relief in surgical and/or non-surgical treatment modalities and are still experiencing pain that interferes with activities of daily living and are also unwilling to undergo or ineligible for total knee replacement due to age or absence of advanced osteoarthritis.”

The probable benefits outweigh the probable risks for the MISHA™ Knee System. The device provides benefits, and the risks can be mitigated by the use of the general controls and the identified special controls.

CONCLUSION

The De Novo request for the MISHA™ Knee System is granted and the device is classified as follows:

Product Code: QVV

Device Type: Medial knee implanted shock absorber

Regulation Number: 21 CFR 888.3610

Class: II