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Summary of Safety and Effectiveness

Sponsor: Zimmer, Inc.
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Date: May 30, 2012

Trade Name: *Vivacit-E*[®] Vitamin E Highly Crosslinked
Polyethylene Liners

Common Name: Total Hip Prosthesis

**Classification Name
and Reference:**

- LPH - Prosthesis, Hip, Semi-constrained,
metal/polymer, porous, uncemented; 21 CFR
888.3358
- JDI - Prosthesis, Hip, Semi-constrained,
metal/polymer, cemented; 21 CFR 888.3350
- LZO - Prosthesis, Hip, Semi-constrained,
metal/ceramic/polymer, cemented or non-porous,
uncemented; 21 CFR 888.3353
- OQG – Hip Prosthesis, Semi-Constrained,
Cemented, Metal/Polymer, + Additive, Porous,
Uncemented; 21 CFR 888.3358
- OQH – Hip, Semi-Constrained, Cemented,
Metal/Polymer + Additive, Cemented; 21 CFR
888.3350
- OQI – Hip, Semi-Constrained, Cemented,
Metal/Ceramic/Polymer + Additive, Porous
Uncemented; 21 CFR 888.3353

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Predicate Device:

Continuum and *Trilogy* Integrated Taper (IT) Acetabular Systems, manufactured by Zimmer, Inc. (K091508)

Longevity IT Highly Crosslinked Polyethylene Elevated Liners, manufactured by Zimmer, Inc. (K093846)

Continuum and *Trilogy* Integrated Taper (IT) Acetabular Systems and *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners, manufactured by Zimmer, Inc. (K101229)

Continuum and *Trilogy* Integrated Taper (IT) Acetabular Systems and *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners, manufactured by Zimmer, Inc. (K103662)

Trilogy Acetabular System *Longevity* Crosslinked Polyethylene Liners manufactured by Zimmer, Inc. (K990135)

E1 Antioxidant Infused Technology, manufactured by Biomet Manufacturing Corp. (K100048)

Device Description:

The *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene Liners are neutral and elevated acetabular liners which are intended to mate with either the *Continuum* or *Trilogy* IT acetabular shells in total hip arthroplasty.

Intended Use:

The *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene Liners are indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, *protrusio acetabuli*, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

The system is intended for use either with or without bone cement in total hip arthroplasty.

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Comparison to Predicate Device:

The *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene Liners are packaged, manufactured, and sterilized using equivalent materials and processes as their predicates. The subject device also has the same intended use as the predicate device.

The subject devices are designed to have the same geometry as the predicate *Longevity* IT Neutral and Elevated liners.

Performance Data (Nonclinical and/or Clinical):

The following non-clinical laboratory testing was performed to determine substantial equivalence: mechanical material characterization (tensile, small punch, Izod Impact, Crack Propagation), physical and chemical characterization (Oxidation Index, Compressive Modulus, Poisson's Ratio, Surface Roughness, Density, Onset Melting Temperature, Peak Melting Temperature, Degree of Crystallinity, Crosslink Density, Swell Ratio, Molecular Weight, Lamellae Thickness, Free Radical concentration, Vitamin E Consolidation, Vitamin E Elution and Extraction, Trans-vinylene Index), biocompatibility (cytotoxicity, systemic toxicity, bacterial reverse mutation, genotoxicity, peripheral blood micronucleus, intracutaneous reactivity, guinea pig maximization sensitization, muscle implantation, acute systemic toxicity, subchronic toxicity, chronic toxicity, and biological response to wear debris studies), wear testing under normal and abrasive conditions, liner push-out, lever-out, and torque-out resistance, fit condition assessment, compatibility in the MR Environment, locking mechanism durability assessment, pendulum frictional torque tests under normal and abrasive conditions, delamination assessment, anatomic fatigue, and subluxed loading fatigue.

Testing was conducted on the subject devices and compared to legally marketed devices. Additionally, evaluations of the device design and geometry were performed. The *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene Liners functioned as intended and met the performance requirements,

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thus demonstrating that the *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene Liners are as safe and effective as the predicate device. These analyses and testing data forms the basis for the determination of substantial equivalence.

Claims:

Claim 1:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene is formulated with antioxidant protection that prevents oxidation degradation of polyethylene.**

Vivacit-E Vitamin E Highly Crosslinked Polyethylene (UHMWPE resin blended with d/l alpha tocopherol, compression molded, crosslinked with electron beam irradiation) tensile (ASTM D638), izod impact (ASTM F648, Annex A1), and oxidation index (ASTM F2102) samples were tested in the non-aged condition as well as at various intervals up to 24 weeks of accelerated aging according to ASTM F2003. The *Vivacit-E* Vitamin E HXPE material showed no significant change in tensile or izod properties and no detectable oxidation (oxidation indices < 0.01) at any aging interval up to 24 weeks. The standard accelerated aging cycle per ASTM F2003 is an aggressive aging method, where samples are subjected to 100% oxygen, 73 psi, and 70°C for two weeks in order to force oxygen into the material in an attempt to elicit an oxidative response. *Vivacit-E* Vitamin E HXPE samples showed no statistically significant difference in ultimate tensile strength ($p=0.63$), elongation ($p=0.61$), and izod impact ($p=0.47$) after aging for 12 times the standard accelerated aging method. Greater than 96% retention of mechanical properties was seen when comparing non-aged to 24-week aged samples, indicating no significant change in mechanical properties after aging.

Additionally, the *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene (UHMWPE resin blended with d/l alpha tocopherol, compression molded, crosslinked with electron beam irradiation) material was subjected to cyclic loading in an oxidative environment. A 0.5 Hz, 10 MPa bending stress was applied at 80°C in an air atmosphere for 5 weeks (~1.5Mc). The *Vivacit-E* material showed no evidence of cracking and negligible oxidation (oxidation indices < 0.05) in the loaded and unloaded samples when tested according to ASTM F2102. *Bench testing is not necessarily indicative of clinical performance.*

Claim 2:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene showed no measurable oxidation during accelerated aging testing per ASTM F2003.**

Vivacit-E Vitamin E Highly Crosslinked Polyethylene was manufactured by blending UHMWPE with d/l alpha tocopherol, compression molding, and crosslinking with electron beam irradiation. Both non-aged samples and samples that were accelerated aged according to ASTM F2003 at 70°C, 73 psi, and 100% oxygen at various aging intervals up to 24 weeks were tested for oxidation index (ASTM F2102) and oxidative

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induction time (ASTM D3895). Conventional GUR 1050 gamma sterilized samples were used as controls. The oxidative induction time is an assessment of how long it takes a material to oxidize at a high temperature. The standard accelerated aging cycle per ASTM F2003 lasts two weeks and is an aggressive aging method, where oxygen is forced into the material in an attempt to elicit an oxidative response. After aging 12 times the standard method, the *Vivacit-E* Vitamin E HXPE samples showed no detectable oxidation (oxidation indices <0.01) and oxidative induction times that were > 8.0 minutes. After 2 weeks of aging, the conventional GUR 1050 samples showed detectable oxidation with an OI greater than 0.5 and oxidative induction times that were less than 1.0 minute. After 4 weeks aging, the conventional GUR 1050 samples showed oxidation indices greater than 3 and oxidation induction time could not be measured due to the brittleness of the material. The oxidative induction times and oxidation indices after accelerated aging for 24 weeks indicate that the presence of Vitamin E in the *Vivacit-E* Vitamin E HXPE material actively and continuously prevents oxidation of the material after an extreme oxidative challenge. *Bench testing is not necessarily indicative of clinical performance.*

Claim 3:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene retains mechanical strength after accelerated aging.**

Vivacit-E Vitamin E Highly Crosslinked Polyethylene (UHMWPE resin blended with d/l alpha tocopherol, compression molded, crosslinked with electron beam irradiation) tensile (ASTM D638) and izod impact (ASTM F648, Annex A1) specimens were tested in the non-aged condition and at various aging intervals up to 24 weeks. Accelerated aging was performed according to ASTM F2003 in 100% oxygen at 73 psi and 70°C. The accelerated aging interval according to ASTM F2003 is two weeks and is an aggressive aging mechanism that attempts to force oxygen into the material to elicit an oxidative response. Once the oxidation process reaches a critical level, it can lead to a decline in mechanical properties. *Vivacit-E* Vitamin E HXPE material showed no statistically significant difference in ultimate tensile strength ($p=0.63$), elongation ($p=0.61$), and izod impact ($p=0.47$) after aging for 12 times the standard accelerated aging method. Greater than 96% retention of mechanical properties was seen when comparing non-aged to 24-week aged *Vivacit-E* Vitamin E HXPE samples, indicating no significant change in properties after aging. *Bench testing is not necessarily indicative of clinical performance.*

Claim 4:

Vitamin E does not elute from *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene.

Several exhaustive solvent extractions for up to 3 days were conducted on *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene (UHMWPE resin blended with d/l alpha tocopherol, compression molded, crosslinked with electron beam irradiation). Solvents included boiling hexane for three days, and isopropanol at room temperature for three

days. Fourier transform infrared with detection limits of 100 ppm, gas chromatography-mass spectroscopy (GC-MS) with detection limits of 10 ppm and liquid chromatography-mass spectroscopy (LC-MS) analysis with detection limits of 10 ppm were used to quantify and identify the extraction residues. The various techniques showed that residue quantities removed from the *Vivacit-E* material were comparable to a non-Vitamin E predicate material. The FTIR spectral analysis of the residues indicated a strong correlation to aliphatic hydrocarbons and any trace amounts of Vitamin E related peaks were within the noise of the instrument.

The Vitamin E blended into UHMWPE material does not elute from the *Vivacit-E* Vitamin E HXPE material after a 24 week exposure to an aqueous environment. The *Vivacit-E* Vitamin E HXPE material was machined into acetabular liners. The *Vivacit-E* Vitamin E HXPE liners were immersed in 40°C de-ionized water for up to a 24 week exposure time. The liners were removed after immersion for 1, 2, 4, 8, 12 and 24 weeks. A sample of the de-ionized water solution was taken at every time interval and measured by UV-Vis for Vitamin E. The Vitamin E levels in the aqueous solution were below detectable limits of UV-Vis. Vitamin E Index and Oxidation Index (ASTM F 2102) were also measured on the liners at each time interval. All results showed no change in Vitamin E Index or Oxidation Index after a 24 week exposure.

The Vitamin E blended into UHMWPE material does not elute from the Vitamin E HXPE material under compressive loading conditions. The pressure induced leaching study was based on the work presented by Okubo et al. "Confirmation of Pressure-Induced Leaching of Vitamin E from inside of Ultra High Molecular Weight Polyethylene" *J. Biomech. Sci. and Eng.*, 5, 154 (2010). Thin films (100 micron thick) were cut from *Vivacit-E* Vitamin E HXPE molded blocks. A vertical compressive load was applied to the film with a metal cylindrical rod. The load conditions were set at two different loads of 150 N and 1500 N for one minute which results in 3 MPa and 30 MPa of contact stress. The transfer film was removed with ethanol and analyzed by fluorescence spectroscopy. The Vitamin E levels under the pressure-induced leaching conditions were below the detection limits of fluorescence spectroscopy. *Bench testing is not necessarily indicative of clinical performance.*

Claim 5:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene resists cracking and oxidation when subjected to environmental stress cracking.**

The *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene (UHMWPE resin blended with d/l alpha tocopherol, compression molded, crosslinked with electron beam irradiation) material was subjected to cyclic loading in an oxidative environment. A 0.5 Hz, 10 MPa bending stress was applied at 80°C in an air atmosphere for 5 weeks (~1.5Mc). The *Vivacit-E* material showed no evidence of cracking and negligible oxidation (oxidation indices <0.05) in the loaded and unloaded samples when tested according to ASTM F2102. *Bench testing is not necessarily indicative of clinical performance.*

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Claim 6:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene retains wear properties after extended aging.**

A test of *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene was conducted comparing in-vitro wear of the material after 2 weeks and 6 weeks of accelerated aging in an aging bomb at 70° C, 73 psi, and 100% oxygen according to ASTM F2003. *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene was prepared by blending UHMWPE flake with d/l alpha-tocopherol, compression molded, crosslinked with e-beam irradiation and sterilized with ethylene oxide. Wear testing was carried out in a 12-station AMTI (Watertown, MA) hip simulator in accordance with ISO-14242-1 for 5 million cycles at a frequency of 1.0±0.1 Hz. A 32 mm CoCr femoral head mated with a 48mm x 32mm *Vivacit-E* neutral liner (4.7mm thickness) and a 48mm x 32mm *Trilogy* conventional neutral liner (4.9mm thickness) was utilized for the testing. All samples were submersed in bovine calf serum diluted with deionized water to a protein content of 30 g/l. 3 g/l sodium azide and 7.9 g/l disodium EDTA was also added to deter bacterial growth and to prevent precipitation of naturally occurring compounds. The average weight loss (mg) was determined gravimetrically and load soak controls (samples that were submersed in the lubricant and placed under the same loading profile, but no articular motions) were used to correct for the fluid absorption properties of the polyethylene components. After 5 million cycles, the volumetric wear rates (weight loss rate divided by the material density, mm³/Mc) of the 2 week aged (1.96±0.34 mm³/Mc) and 6 week aged (1.50±0.32 mm³/Mc) *Vivacit-E* Vitamin E HXPE liners were not statistically different from each other (p=0.064); thus indicating that *Vivacit-E* Vitamin E HXPE retains wear properties after extended aging. *The results of in-vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.*

Claim 7:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene has wear properties which are comparable to *Longevity* Highly Crosslinked Polyethylene.**

In-vitro wear testing was undertaken to evaluate the wear performance of *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene liners in comparison to *Longevity* IT liners. *Vivacit-E* Vitamin E HXPE was prepared by blending UHMWPE flake with d/l alpha-tocopherol, compression molding, crosslinking with e-beam irradiation and sterilizing with ethylene oxide. The largest articulation size (56mm x 40mm acetabular liner (4.7mm thickness) mated with a 40mm CoCr femoral head and 56mm uni-hole *Continuum* acetabular shell) of the *Vivacit-E* Vitamin E and *Longevity* IT HXPE liners was chosen as it constitutes the worst case size for wear. Both *Vivacit-E* and *Longevity* were accelerated aged for 2 weeks prior to evaluation at 70°C, 73 psi, and 100% oxygen according to ASTM F2003. All liners were tested in a 12-station AMTI (Watertown, MA) hip simulator in accordance with ISO-14242-1 for 5 million cycles at a frequency of 1.0±0.1Hz. All samples were submersed in bovine calf serum diluted with deionized water to a protein content of 30 g/l. 3 g/l sodium azide and 7.9 g/l disodium EDTA was also added to deter bacterial growth and to prevent precipitation of naturally occurring

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compounds. The average weight loss (mg) was determined gravimetrically and load-soak controls (samples that were submersed in the lubricant and placed under the same loading profile, but no articular motions) were used to correct for the fluid absorption properties of the polyethylene components. The wear rates (weight loss rate divided by the material density based off a linear best fit line to the data, mm^3/Mc) exhibited by the *Vivacit-E* and *Longevity* material, $1.02 \pm 0.39 \text{ mm}^3/\text{Mc}$ and $1.56 \pm 0.33 \text{ mm}^3/\text{Mc}$ respectively, were not statistically different from each other ($p=0.165$). *The results of in-vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.*

Claim 8:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene showed a 96% reduction in wear over Conventional Polyethylene.**

In-vitro wear testing was undertaken to evaluate the reduction in wear of *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene over Conventional Polyethylene. *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene was prepared by blending UHMWPE flake with d/l alpha-tocopherol, compression molding, crosslinking with e-beam irradiation and sterilizing with ethylene oxide. The Conventional Polyethylene material tested was compression molded, gamma sterilized UHMWPE. 40mm articulation size *Vivacit-E* Vitamin E HXPE (average of best and worst case formulation) liners (56mm x 40mm neutral liners (4.7mm thickness) mated with a 40mm CoCr femoral heads) and 32mm articulation sized Conventional Polyethylene liners (48mm x 32mm conventional neutral liners (4.9mm thickness) mated with 32mm CoCr femoral heads) were tested in a 12-station AMTI (Watertown, MA) hip simulator in accordance with ISO-14242-1 for 5 million cycles (Mc) at a frequency of $1.0 \pm 0.1 \text{ Hz}$. All samples were submersed in bovine calf serum diluted with deionized water to a protein content of 30 g/l. 3 g/l sodium azide and 7.9 g/l disodium EDTA was also added to deter bacterial growth and to prevent precipitation of naturally occurring compounds. The average weight loss (mg) was determined gravimetrically and load soak controls (samples that were submersed in the lubricant and placed under the same loading profile, but no articular motions) were used to correct for the fluid absorption properties of the polyethylene components. Both materials were accelerated aged for 2 weeks in an aging bomb at 70°C, 73 psi, and 100% oxygen according to ASTM F2003 prior to testing. The average volumetric wear rates (mm^3/Mc) calculated after 5 million cycles showed that the 40mm *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene liners displayed a 96% reduction in wear compared to the 32mm Conventional Polyethylene components. *The results of in-vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.*

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Claim 9:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene and *Longevity* Highly Crosslinked Polyethylene wear particles elicited comparable local and systemic inflammatory responses in rabbits.**

A study was conducted to evaluate the effects of *Vivacit-E* Vitamin E HXPE wear debris in the knee following percutaneous injection at 3 and 6 month time intervals. The testing was performed on healthy white rabbits. Particles of crosslinked ultra-high molecular weight polyethylene (UHMWPE) material suspended in 67% Buffered Blood Bank Saline (BBBS) and 33% ethanol were used as the control article to compare to a high and low dose particle count of *Vivacit-E* Vitamin E HXPE suspended in BBBS. The *Vivacit-E* Vitamin E HXPE particles were generated using both wear simulators and mechanical grinders from UHMWPE resin blended with d/l alpha tocopherol, compression molded, and crosslinked with electron beam irradiation. Sterile, injection ready suspensions of particles from each test material were prepared. Physiologically relevant, in both size and quantity, particle suspensions were prepared based on published in-vivo clinical retrieval studies and normalized for rabbit body weight and joint size. On the day of dosing, approximately 150 μ L of each of the four article suspensions (UHMWPE control, vehicle control (33.3% ethanol+BBBS), high dose *Vivacit-E* HXPE, and low dose *Vivacit-E* HXPE) were injected into the lateral-anterior aspect of the right and left hind knee joint of rabbits. Blood samples were taken just prior to euthanizing the animals at both time interval endpoints of 3 and 6 months. The knee joint was dissected free and removed in toto as well as the popliteal lymph nodes, inguinal lymph nodes, spleen and liver. Under the conditions of this study, local and systemic inflammatory response was similar for both the *Vivacit-E* HXPE and UHMWPE control following intraarticular injection in rabbits for 3 and 6 months duration. Additionally, the *Vivacit-E* HXPE did not cause systemic toxicity in this study. Microscopically, the test articles were classified as a nonirritant as compared to the vehicle and the UHMWPE control article at the 3 and 6 month termination intervals. *Animal testing is not necessarily indicative of clinical performance.*

Claim 10:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene is classified as a non-irritant as compared to the control under the conditions of a muscle implantation study.**

Intramuscular implant testing was performed per ISO 10993 on healthy white rabbits at both 2 week and 12 week time periods. Four *Vivacit-E* Vitamin E HXPE sites and four HDPE sites were implanted for each rabbit at each time interval. The surgical sites were closed and the animals were observed daily for either 2 weeks or 12 weeks. A veterinary pathologist microscopically evaluated the H&E stained tissue sections of each implant site and concluded the macroscopic reaction was not significant as compared to the negative control article at both time intervals. The average irritant scores for HDPE and *Vivacit-E* Vitamin E HXPE were 7.0 and 7.0 respectively at 2 weeks and 3.7 and 3.0 respectively at 12 weeks. The Irritant Ranking Score is defined as: Test Group Average

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- Control Group Average. For the two week interval, $7.0 - 7.0 = 0$ and for the twelve week interval, $3.0 - 3.7 = 0 (-.7)$. According to the interpretation of the Irritant Ranking Score, a non-irritant is classified as having a range of 0.0 - 2.9. Therefore, with Irritant Ranking Scores of 0.0 and -0.7, *Vivacit-E* Vitamin E HXPE is classified as a non-irritant. *Animal testing is not necessarily indicative of clinical performance.*

Claim 11:

***Vivacit-E* Vitamin E Highly Crosslinked Polyethylene did not elicit systemic toxicity in the mammalian animal model as compared to the control.**

Acute systemic toxicity testing was performed per ISO 10993 on healthy adult mice.

The *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene (UHMWPE resin blended with d/l alpha tocopherol and compression molded) material was extracted in both a polar and non-polar solvent. The study used a control blank of extraction vehicle without the test article. A single dose of either test article extract or control blank was injected into each animal. Animals were observed for any adverse clinical reactions immediately after injection and then again at 4, 24, 48, and 72 hours after injection. The animals were weighed daily after dosing. There was no mortality or evidence of systemic toxicity from the extracts and the *Vivacit-E* Vitamin E HXPE extracts met the requirements of the study.

Subchronic systemic toxicity testing was performed per ISO 10993 on healthy adult male and female rats.

A USP high density polyethylene (HDPE) reference standard material was used as the control article to compare to *Vivacit-E* Vitamin E HXPE. The *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene (UHMWPE resin blended with d/l alpha tocopherol and compression molded) material and HDPE reference material were surgically implanted in the subcutaneous tissue of the rat. Detailed examinations for clinical signs of disease or abnormality were conducted at pretreatment and weekly thereafter. Body weights of the test subjects were recorded at pretreatment, weekly, and the day prior to termination (pre-fasted weight) and the day of termination (fasted weight). At 13 weeks, blood samples were taken from each rat for hematology and clinical chemistry analyses. The animals were then euthanized, each implant was excised, and tissue samples were collected, weighed, and preserved. There was no evidence of systemic toxicity from the *Vivacit-E* Vitamin E HXPE following subcutaneous implantation in the rat for 13 weeks. The local macroscopic tissue reaction was not significant compared to the control article. Macroscopically, the *Vivacit-E* Vitamin E HXPE was classified as a non-irritant as compared to the control article.

Chronic systemic toxicity testing was performed per ISO 10993 on healthy adult male and female rats.

A USP high density polyethylene (HDPE) reference standard material was used as the control article to compare to *Vivacit-E* Vitamin E HXPE. The *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene (UHMWPE resin blended with d/l alpha tocopherol and compression-molded) material and HDPE reference material were surgically implanted in

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the subcutaneous tissue of the rat. Detailed examinations for clinical signs of disease or abnormality were conducted at pretreatment and weekly thereafter. Body weights of the test subjects were recorded at pretreatment, weekly, and the day prior to termination (pre-fasted weight) and the day of termination (fasted weight). At 26 weeks, blood samples were taken from each rat for hematology and clinical chemistry analyses. The animals were then euthanized, each implant was excised, and tissue samples were collected, weighed, and preserved. Macroscopic and microscopic findings showed no evidence of systemic toxicity from the *Vivacit-E* Vitamin E HXPE following subcutaneous implantation in the rat for 26 weeks. Macroscopic evaluation of the implantation sites showed no irritation in both the *Vivacit-E* Vitamin E HXPE and control materials. The local macroscopic tissue reaction was not significant compared to the control article. Microscopic evaluation of the subcutaneous tissue from the implantation site was found that the tissue response to *Vivacit-E* Vitamin E HXPE was comparable to that of the control material. The study classified *Vivacit-E* Vitamin E HXPE as a non-irritant as compared to the control article. *Animal testing is not necessarily indicative of clinical performance.*

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

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Indications for Use

510(k) Number (if known): K120370

Device Name:

*Vivacit-E*TM Vitamin E Highly Crosslinked Polyethylene Liners

Indications for Use:

The system is indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

The system is intended for use either with or without bone cement in total hip arthroplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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