August 29, 2018

OsteoRemedies, LLC
% Hollace Rhodes
Senior Director, Orthopedic Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street, Suite 1000
Washington, District of Columbia 20001

Re: K172906
Trade/Device Name: REMEDY PLUS Hip Spacer, UNITE PLUS Bone Cement
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWL, KWY, MBB
Dated: September 22, 2017
Received: September 22, 2017

Dear Hollace Rhodes:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K172906

Device Name
REMEDY PLUS Hip Spacer

Indications for Use *(Describe)*

The REMEDY PLUS Hip Spacer, which consists of a modular head and stem, is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin and vancomycin are the most appropriate antibiotics based on the susceptibility pattern of the infecting micro-organism(s).

The head and stem components are inserted into the acetabular cavity and femoral medullary canal, respectively, following removal of the existing acetabular and femoral components and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The REMEDY PLUS Hip Spacer is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K172906

Device Name
UNITE PLUS Bone Cement

Indications for Use *(Describe)*
The UNITE PLUS Bone Cement is intended for the fixation of a REMEDY PLUS spacer devices to the host bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for
REMEDY PLUS Hip Spacer and UNITE PLUS Bone Cement

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Date Prepared: August 29, 2018

Trade/Proprietary Names: REMEDY PLUS Hip Spacer
UNITE PLUS Bone Cement

Common/Usual Names: Hip Spacer
PMMA bone cement with antibiotic for orthopedics

Classification Information: Class II

21 CFR 888.3360, Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

21 CFR 888.3027, Polymethylmethacrylate (PMMA) bone cement

Product Codes: KWL, KWY, and MBB for the REMEDY PLUS Hip Spacer

MBB for the UNITE PLUS Bone Cement

Predicate Devices: DePuy Prostalac Hip Temporary Prosthesis System

NP Cements Genta HV Bone Cements (K143100)

Reference Device: REMEDY Hip Spacer cleared as the 2GC Hip Modular Spacer (K112470)

Device Description:

The REMEDY PLUS Hip Spacer is comprised of modular components, which are available in different sizes to accommodate variations in patient anatomy. The REMEDY PLUS Hip Spacer includes stems in various sizes and lengths, and femoral heads in various diameters. The modular design of the REMEDY PLUS Hip Spacer allows the surgeon to choose a femoral head offset which best matches the patient's anatomy.

The REMEDY PLUS Hip Spacer is a sterile, single-use device intended for temporary use (maximum 180 days) as a joint replacement. The implants are made of fully formed polymethylmethacrylate (PMMA), which is radiopaque, and contains gentamicin and vancomycin. The hip device has an inner stainless steel (AISI 316 ESR stainless steel) reinforcing structure.

The UNITE PLUS Bone Cement is a PMMA, radiopaque bone cement, containing gentamicin and vancomycin, designed for the fixation of prosthesis to the living bone. The UNITE PLUS Bone Cement is provided sterile.

Indications for Use and Intended Use:

REMEDY PLUS Hip Spacer

The REMEDY PLUS Hip Spacer, which consists of a modular head and stem, is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin and vancomycin are the most appropriate antibiotics based on the susceptibility pattern of the infecting micro-organism(s).

The head and stem components are inserted into the acetabular cavity and femoral medullary canal, respectively, following removal of the existing acetabular and femoral components and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The REMEDY PLUS Hip Spacer is not intended for use for more than 180 days, at which time it must be explanted, and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.).

UNITE PLUS Bone Cement

The UNITE PLUS Bone Cement is intended for the fixation of a REMEDY PLUS spacer device to the host bone.

Substantial Equivalence Comparison Overview

REMEDY PLUS Hip Spacer

The REMEDY PLUS Hip Spacer is similar to the predicate device with respect to the following:

1) the same intended use in the same surgical procedures in the same target patient population
2) similar overall design, having same geometry and sizes as the REMEDY Hip Spacer
3) similar manufacturing processes and steps at the same manufacturing facility as the REMEDY Hip Spacer
4) similar mechanical performance characteristics
5) similar clinical performance, and
6) similar instructions for use and draft labeling.

There are differences between the REMEDY PLUS Hip Spacer and the predicate device, though these differences, shown through pre-clinical and clinical information, do not adversely impact the substantial equivalence of the subject device. Specifically:

1) the REMEDY PLUS Hip Spacer has gentamicin and vancomycin; the REMEDY Hip Spacer contains gentamicin; and the 2-antibiotic predicate contains tobramycin and vancomycin added at time of implantation.
2) the REMEDY PLUS Hip Spacer and REMEDY Hip Spacer are pre-made spacers; the 2-antibiotic predicate is molded intra-operatively.

Please see the Performance Testing Overview and Clinical Study Overview for comparison data supporting the substantial equivalence of the REMEDY PLUS Hip Spacer implanted with UNITE PLUS Bone Cement compared to predicate spacers.

UNITE PLUS Bone Cement

The UNITE PLUS Bone Cement device is similar to the predicate device with respect to the following:

1) both are antibiotic-loaded bone cements
2) similar main cement components
3) similar manufacturing processes and steps at the same manufacturing facility
4) similar mechanical performance characteristics, and
5) similar *in vitro* and *in vivo* elution profiles.

There are differences between the UNITE PLUS Bone Cement, NP Cements Genta HV Bone Cement, and cement used to fix the 2-antibiotic predicate, though these differences do not impact the substantial equivalence of the subject device relative to the predicate. Specifically:

1) UNITE PLUS Bone Cement has gentamicin and vancomycin; the NP Cements Genta HV Bone Cement contains only gentamicin; and the cement used to fix the 2-antibiotic spacer contains tobramycin and vancomycin
2) UNITE PLUS Bone Cement is intended for the fixation of REMEDY PLUS Spacer device to the host bone; NP Cements Genta HV Bone Cement is intended for the fixation of the prosthesis to the living bone in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared; cement mixed intra-operatively with tobramycin and vancomycin is used for the fixation of the 2-antibiotic spacer, and
3) UNITE PLUS Bone Cement does not have the colorants used in NP Cements Genta HV Bone Cement.

Please see the Performance Testing Overview and Clinical Study Overview for comparison data supporting the substantial equivalence of the REMEDY PLUS Hip Spacer implanted with UNITE PLUS Bone Cement compared to the predicate spacer.

Performance Testing Overview:

Performance data for the REMEDY PLUS Hip Spacer, the UNITE PLUS Bone Cement, and their predicate devices demonstrate their substantial equivalence. The following testing was performed:

- Stem fatigue per ISO 7206-4
- Neck fatigue per ISO 7206-6
- Femoral head/stem disassembly based on ISO 7206-13
- Chemical and physical properties of cement
- Antibiotic elution kinetics
- Clinical data
- Biocompatibility data
- Sterilization, pyrogenicity, bacterial endotoxin, and shelf life testing

Clinical Study Overview:

Prospective and retrospective data were collected outside of the United States on subjects with a diagnosis of periprosthetic joint infection (PJI) who were implanted with an antibiotic spacer during the first stage of a two-stage revision due to a PJI. One antibiotic spacer contained gentamicin and vancomycin ("GV Spacer") having data collected prospectively. The other one contained gentamicin only ("G Spacer") having the majority of its data collected retrospectively, but some prospectively. The antibiotic formulation and PMMA in the GV Spacer are identical to the REMEDY PLUS Spacers. The antibiotic formulation and PMMA in the G Spacer are identical to the REMEDY Spacers. The study included 49 subjects (26 hips and 23 knees) implanted with the GV Spacer, and 81 subjects (51 hips and 31 knees) implanted with the G Spacer which is 510(k)-cleared though has only one antibiotic. The GV and G spacer data were also compared to the predicate hip spacer and literature data.

Composite Endpoint (Stage 1/Stage 2 Success)

Success for the composite endpoint required Stage 1 success (i.e., absence of Girdlestone (hip fusion), arthrodesis (knee fusion), amputation, or spacer-related death) and Stage 2 success (i.e., absence of two or more positive cultures of microorganisms at the time of reimplantation with the definitive implant).

Composite Success (Stage 1 / Stage 2 Success)

All Subjects	**GV Spacer**			**G Spacer**			**Dif.**	
	N[a]	**n[b]**	**%**	**N**	**n**	**%**	**%**	**p-value**
Composite – All Evaluable (N=129)[1]	48	43	89.6%	81	58	71.6%	18%	0.0126[2]
Composite – MI (N=130)[3]	49	---	89.2%	81	58	71.6%	17.6%	0.0105[4]
Hip Subjects	**GV Spacer**			**G Spacer**			**Dif.**	
	N	**n**	**%**	**N**	**n**	**%**	**%**	**p-value**
Composite (N=76)	25	21	84%	51	34	66.7%	17.3%	

[1] For this comparison, one patient with good clinical status but with no reimplantation with a definitive implant was defined as a composite success and one patient with unrelated death prior to reimplantation with a definitive implant were censored.

[2] One-sided Fisher's Exact Test.

[3] The number of successes is not reported for GV Spacer under MI (multiple imputation). 89.2% is the average across 20 MIs. For this comparison, the outcome for one GV patient with unrelated death prior to reimplantation with a definitive implant was imputed.

[4] One-sided T-test from MI taking into account between and within imputation variance.

[a] N = All subjects implanted with each type of spacer. Definition applies to all tables.

[b] n = All subjects meeting the specified endpoint. Definition applies to all tables.

For the "All Subjects" cohort, the composite success rate for the GV Spacer is significantly higher than the composite success rate for the G Spacer for both the "all evaluable" and "multiple imputation" analyses. For the "Hip Subjects" cohort, the composite success rate for the GV Spacer is 17.3% higher than the composite success rate for the G Spacer.

A composite endpoint based on Stage 1 and Stage 2 outcomes was not defined for the retrospective study of the 2-antibiotic predicate. Nonetheless, it is reasonable to consider the absence of persistent/recurrent infection at both Stage 1 and Stage 2 as a composite endpoint. At Stage 1, the absence of infection rate is 91.1% (123/135); at Stage 2, the rate is 89.3% (100/112). Combined, the predicate success rate is 82.2% for Stage 1 and Stage 2 which is comparable to the composite success rate for the GV Spacer.

In the Rothman Institute publication (*Gomez, et al., 2015*), "Retrospective multi-center study on outcomes of PJI patients treated with various antibiotic cement spacers", outcomes were captured for 504 hip and knee PJI subjects. A Stage 1 success rate was calculated using the same definition used in the GV vs. G study (i.e., absence of Girdlestone, arthrodesis, amputation, or death). When the lost-to-follow-up subjects (n=19) are excluded, the Stage 1 success rate was calculated to be 89.5% (434/485) which includes 417 subjects who were reimplanted and 17 patients with retained spacers who were considered to be treatment successes. When the lost-to-follow-up subjects (n=85) are excluded, the Stage 2 success rate was calculated to be 80.7% (268/332). Overall composite success requires success at both stages. When the lost-to-follow-up subjects are excluded at both stages, the overall

composite success rate for Stage 1 and Stage 2 was calculated to be 71.3% (285/400) which is lower than the composite success rate for the GV Spacer.

Stage 1 Outcomes

Success at Stage 1 is defined as the absence of Girdlestone (hip fusion), arthrodesis (knee fusion), amputation, or spacer-related death.

Stage 1 Outcomes

All Subjects	**GV Spacer**			**G Spacer**			**Diff.**	**Exact**
	N	**n**	**%**	**N**	**n**	**%**	**%**	**p-value***
Total Enrolled	**49**			**81**				
Unrelated deaths	**1**			**0**				
Stage 1 Successes	**48**	**44**	**91.7%**	**81**	**69**	**85.2%**	**6.5%**	**0.213**
THA	25	22	88%	51	43	84.3%		
TKA	23	22	95.7%	30	26	86.7%		
Stage 1 Failures	**48**	**4**	**8.3%**	**81**	**12**	**14.8%**	**-6.5%**	
Girdlestone	48	2	4.2%	81	8	9.9%		
Arthrodesis	48	0	0%	81	3	3.7%		
Amputation	48	1	2.1%	81	1	1.2%		
Death	48	1	2.1%	81	0	0%		
Hip Subjects	**GV Spacer**			**G Spacer**			**Diff.**	
	N	**n**	**%**	**N**	**n**	**%**	**%**	
Total Enrolled	**26**			**51**				
Unrelated deaths	**1**			**0**				
Stage 1 THA Successes	**25**	**22**	**88%**	51	43	84.3%	**3.7%**	
Stage 1 Failures	**25**	**3**	**12%**	**51**	**8**	**15.7%**	**-3.7%**	
Girdlestone	25	2	8%	51	8	15.7%		
Death	25	1	4%	51	0	0%		

*Two-sided Fisher's Exact p-value.

For the "All Subjects" cohort, the rate of Stage 1 success for the GV Spacer cohort is 91.7% which is higher than the Stage 1 success rate of 85.2% for the G Spacer cohort, though this difference is not significant (two-sided Fisher's Exact p=0.213). For the "Hip Subjects" cohort, the Stage 1 success rate for the GV Spacer is 3.7% higher than the Stage 1 success rate for the G Spacer.

The outcomes for the GV Spacer were also compared to: (1) a retrospective study of 135 patients implanted with the 2-antibiotic predicate, and (2) literature.

At Stage 1, 6 (4.4%) of the 135 2-antibiotic predicate subjects had a Girdlestone procedure, 12 (8.9%) had persistent/recurrent deep infections, 8 (5.9%) had an intra-operative bone fracture, and 5 (3.7%) had a post-operative bone fracture. Seventeen (17) of the 135 subjects (12.6%) did not have a reimplantation with a definitive implant. These 17 subjects had a retained predicate, received a second spacer device, or died.

A publication from the Rothman Institute reports on 504 hip and knee PJI subjects. When the lost-to-follow-up subjects (n=19) are excluded, the Stage 1 success rate was calculated to be 89.5% which is comparable to the Stage 1 success rate for the GV Spacer. The 10.5% failure rate included 6 amputations, 5 Girdlestones, 4 arthrodeses, and 36 deaths (*Gomez, et al., 2015*).

Safety – Inter-Stage Reoperations

Inter-stage reoperations included spacer exchanges and debridements.

Inter-stage Reoperations

All Subjects	**GV Spacer**			**G Spacer**		
	N	**n**	**%**	**N**	**n**	**%**
Spacer exchange	48	5	10.4%	81	8	9.9%
Spacer debridement	48	3	6.25%	81	0	0%
Hip Subjects	**GV Spacer**			**G Spacer**		
	N	**n**	**%**	**N**	**n**	**%**
Spacer exchange	25	3	12%	51	6	11.8%
Spacer debridement	25	2	8%	51	0	0%

For both the "All Subjects" and "Hip Subjects" cohorts, the GV and G cohorts exhibit similar rates of spacer exchange. The rate of spacer debridement for the GV Spacer is higher than what is reported for the G spacer.

The inter-stage reoperation rates were also compared to the 2-antibiotic predicate study and literature.

Inter-stage Reoperations

Inter-stage Reoperations	**2-Antibiotic Predicate**			**Gomez (2015)**			**Cancienne (2017)****		
	N	**n**	**%**	**N**	**n**	**%**	**N**	**n**	**%**
Spacer exchange	118	8	6.8%	504	60	11.9%	-	-	-
Spacer debridement	135	*	*	-	-	-	7146	775	10.8%

*Although the number of debridement procedures was not identified for the retrospective study of the predicate, a publication (*Wentworth, et al., 2002*) reports that 12 subjects (8.9%) had persistent/recurrent deep infections at Stage 1.

** Cancienne, J. M. et al. Removal of an Infected Total Hip Arthroplasty: Risk Factors for Repeat Debridement, Long-term Spacer Retention, and Mortality The Journal of Arthroplasty , Volume 32 , Issue 8 , 2519 - 2522.

The inter-stage reoperation rates for the GV Spacer, including spacer exchanges and debridements, are similar to those reported for the predicate and/or literature.

Safety – Acute Kidney Injury (AKI)

In the "All Subjects" cohort, acute kidney injury (AKI) was reported in 5 of the 49 subjects (10.2%) implanted with the GV Spacer, and 3 of the 81 subjects (3.7%) implanted with the G Spacer. These rates are within the range of what is reported in the literature for patients being treated for PJI with antibiotic-loaded spacers (i.e., 8.5%[1] to 20%[2]) (*Reed et al., 2014; Aeng et al., 2015*). Published literature indicates that high-dose antibiotic spacers made in the operating room, such as the predicate, may be associated with a higher risk of nephrotoxicity when compared to preformed, low-dose antibiotic spacers such as the GV Spacer (*Luu et al., 2013; Edelstein et al., 2018*). In the "Hip Subjects"

cohort, AKI was reported in 4 of 25 subjects (16%) implanted with a GV Hip Spacer, and 3 of the 51 subjects (5.9%) of the subjects implanted with the G Spacer. Again, these are within the range of AKI rates reported in the literature for patients undergoing treatment for PJI. One patient with chronic kidney disease, hypertension, and cardiopathy experienced an AKI-related death.

Patients should be monitored for AKI while undergoing treatment for PJI, as the combination of systemic antibiotics, drugs prescribed to treat any comorbidities, and the antibiotics present in the spacer can all contribute to the risk of AKI. Please refer to the warnings and precautions in the package insert for the REMEDY PLUS Hip Spacer for additional information.

Effectiveness – Stage 2 Outcomes

Success at the second stage of a two-stage revision is defined as the absence of two or more positive cultures of microorganisms at the time of reimplantation.

Stage 2 Outcomes

All Subjects	**GV Spacer**			**G Spacer**			**Diff.**	**Exact**
	N	**n**	**%**	**N**	**n**	**%**	**%**	**p-value***
Success at Stage 2	43	42	97.7%	69	58	84.1%	13.6%	0.0198
Hip Subjects	**GV Spacer**			**G Spacer**			**Diff.**	
	N	**n**	**%**	**N**	**n**	**%**	**%**	
Success at Stage 2	22	21	95.5%	43	34	79.1%	16.4%	

*One-sided Fisher's Exact Test.

For the "All Subjects" cohort, the Stage 2 success rate for the GV Spacer of 97.7% is statistically superior to the success rate for the G Spacer of 84.1% (one-sided Fisher's Exact p = 0.0198). For the "Hip Subjects" cohort, the Stage 2 success rate for the GV Spacer was 95.5%, which is 16.4% higher than the Stage 2 success rate for the G Spacer subjects of 79.1%.

In the retrospective study of the 2-antibiotic predicate, a successful *treatment outcome* was defined as no growth of a microorganism on any culture obtained from the operative site during the second stage surgery. A successful *clinical outcome* was defined as implantation of a total hip prosthesis at the second stage surgery with no growth of a microorganism on any culture obtained from the operative site and no reoperations resulting from a recurrent or persistent infection of the affected hip at a minimum of one month postoperatively. Of the 135 subjects enrolled in the retrospective study, 116 were included in the evaluation of Stage 2 success. Of these, 96 (83%) were considered a treatment success. Note: Seventeen (17) of the 135 subjects (12.6%) did not have a reimplantation with a definitive implant. These 17 subjects had a retained spacer device, received a second spacer device, or died. Two additional subjects were excluded from the evaluation of Stage 2 outcomes because their intraoperative cultures could not be confirmed. Successful clinical outcomes were reported for 91.7 percent (89/97) of the cases with the minimum required one-month follow-up.

In the Rothman Institute publication (*Gomez, et al., 2015*), the Stage 2 success rate was calculated to be 80.7% (268/332). The Stage 2 success rate for the GV Spacer compares favorably to the rate reported by Gomez.

Secondary Outcome – Antibiotic Usage

Success at Stage 2 was associated with a shorter mean total duration of systemic antibiotic usage after the second stage surgery. 93% of the GV subjects were finished with their antibiotic course within a week of their second stage surgery. In contrast, only 25% of the G subjects were completed with antibiotics within the first post-operative week after the second stage surgery.

Conclusions:

The nonclinical and clinical testing demonstrates that the REMEDY PLUS Hip Spacer and UNITE PLUS Bone Cement are substantially equivalent to the predicate device.