SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

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1. General Information

Device Generic Name:	Bridge™ Extra Support
Device Trade Name(s):	Bridge™ Extra Support Over-the-Wire (OTW) Renal Stent System Model #'s: XR510, XR610, XR710, XR510L, XR610L, XR710L, XR517, XR617, XR717, XR517L, XR617L, XR717L
Applicant's Name and Address:	Medtronic AVE Peripheral Technologies 3576 Unocal Place Santa Rosa, CA. 95403
Date of Panel Recommendation:	None
Premarket Approval Application (PMA) Number	P020007
Date of notice of Approval to Applicant:	December 18, 2002

2. Indications For Use

The Bridge Extra Support device is indicated for use in patients with atherosclerotic disease of the renal arteries following sub-optimal or failed percutaneous transluminal renal angioplasty (PTRA) of a de novo lesion (≤ 15 mm in length) located within 10 mm of the aortorenal border and with a reference vessel diameter of 5.0 to 7.0 mm. Sub-optimal or failed PTRA include any of the following: visible evidence of a residual stenosis ≥ 50% after optimal PTRA, visible evidence of intimal dissection > 6 mm, or peak systolic trans-stenotic gradient of ≥ 20 mmHg or a mean of ≥ 10 mmHg.

3. Contraindications

There are no known contraindications for the Bridge Extra Support Renal stent.

4. Warnings and Precautions

Long-term outcome (beyond one year) for this permanent implant is unknown at present. The complete warnings and precautions can be found in the Bridge Extra Support labeling.

5. Device Description

The Bridge Extra Support Stent Delivery System consists of a flexible, low profile catheter, a distal balloon which provides a platform for mounting, delivering and deploying the stent, and a balloon expandable stent made from implant grade 316L stainless steel. The stent configurations are based on multiples of 3.4 mm long segments constructed from a continuous toroid ring. The ring is formed into alternating upper and lower crowns with six radiused crowns per end connected by axial struts for a total of twelve crowns and twelve axial struts in a zig zag pattern. The individual segments are connected via laser fusion. The final stent form is then electropolished, inspected, radially compressed, and then mounted onto the balloon portion of the catheter delivery system.

The Bridge Extra Support stent is provided on an Over-the-Wire (OTW) delivery system. Over-the-Wire catheters are defined as catheters that during delivery of the stent, the entire length of catheters is advanced over the guidewire in place. The shaft of the delivery system is coaxial over the entire length of the catheter. The inner lumen of the coaxial catheter is designed to accommodate a maximum guidewire diameter of 0.035 inches. The outer lumen of the coaxial catheter is used for inflation and deflation of the balloon. The proximal end of the catheter contains a luer adapter with two ports; one port is used for accessing the guidewire lumen while the second port facilitates inflation and deflation of the balloon. A strain relief between the proximal shaft and the luer adapter provides rigidity and transition between the two parts.

The Bridge Extra Support stent is offered in diameters of 5.0 mm, 6.0 mm and 7.0 mm and in lengths of 10 and 17mm. The stent are provided pre-mounted on delivery catheters that are available in two lengths: 75 cm and 120 cm.

6. Alternative Practices and Procedures

Alternative practices specific to the treatment of renal atherosclerotic disease are:

- Balloon angioplasty
- Drug therapy (e.g., hypertension medication, antiplatelet agents, and anticoagulant agents)
- Surgical Procedures (e.g., aorto-renal bypass, combined aortic graft and aorto-renal bypass, adjunctive transaortic renal endarterectomy).

7. Marketing History

The Extra Support stent on the OTW delivery system was cleared via pre-market notification in July 1999 as the Bridge Extra Support Biliary Stent Delivery System (K991533) for treatment of bile ducts, occluded by a malignant tumor. Additionally, the 6-crown Extra Support stent and OTW delivery system was introduced into the European Union market in April 1999 as the Bridge Extra Support Renal Stent System. The device

has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

8. Potential Adverse Effects of the Device on Health

The potential adverse effects of using the Bridge Extra Support Stent and Delivery System (as with any other type of intravascular stents and/or vascular implants) include, but are not limited to, the following (in order of severity):

- Death
- Emergent Peripheral Artery Bypass Surgery
- Stroke/Cerebrovascular Accidents
- Stent thrombosis/occlusion
- Total occlusion of renal artery
- Acute myocardial infarction
- Perforation
- Restenosis of stented segment
- Kidney Infarct
- Renal Insuffiency or failure
- Arrhythmias, including VF and VT
- Dissection
- Emboli, distal (air, tissue or thrombotic emboli)
- Rupture of retroperitoneum or of neighboring organ
- Bowel Infarct
- Stent embolization
- Hemorrhage, requiring transfusion
- Arteriovenous fistula
- Pseudoaneurysm, femoral
- Spasm
- Tissue ulceration or necrosis
- Extremity ischemia
- Infection and pain at insertion site
- Hematoma at vascular site
- Drug reactions to antiplatelet agents/contrast medium
- Hypotension/Hypertension

The summaries for observed adverse events are included in Tables 3, 4 and 5.

9. Summary of Pre-clinical Studies

Biocompatibility

The Bridge Extra Support has been determined to be biocompatible.

All biocompatibility testing was conducted on finished, sterile devices. The testing was conducted in compliance with applicable requirements in the Good Laboratory Practice (GLP) regulations 21 CFR Part 58, the 'Guidance for the Submission of Research and

Marketing Applications for Interventional Cardiology Devices' published by the Interventional Cardiology Devices Branch, Division of Cardiovascular, Respiratory and Neurological Devices, Office of Device Evaluation in May 1995, and ISO 10993.

The following tests were conducted on the Bridge Extra Support stent: cytotoxicity, hemolysis, acute systemic toxicity, irritation, sensitization, material mediated pyrogenicity, complement activation, hemocompatibility (coagulation), and thromboresistance. Biocompatibility testing on Medtronic AVE's delivery systems includes cytotoxicity, hemolysis, acute systemic toxicity, irritation, sensitization, material mediated pyrogenicity, complement activation, hemocompatibility (coagulation), and thromboresistance.

All biocompatibility testing met the appropriate acceptance criteria in accordance with ISO10993.

In Vitro Testing

In Vitro testing was conducted in accordance with the FDA ODE "Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents", May 1995.

Table 1: *In Vitro* Test Results

Test	Acceptance Criteria	Bridge Extra Support	N
Material Analysis	Material Analysis – ASTM F138-92 Grade 2 (stainless steel) and ISO 5832-1 Composition D	Pass	1,211 coupon samples
Mechanical Properties	Compare with ASTM F138 UTS - > 70 ksi YS - > 25 ksi Elongation - > 40%	Pass	10 rings
Weld Tensile	Weld Tensile > 3.5 lbs.	Pass	65 welds
Corrosion	No evidence of preferential attack of the grain boundaries.	Pass	41 welds
Stent Free-area	Characterization Only	Greater than 80%	Calculated value
Length Change vs. Diameter	Characterization Only	Results Acceptable	135 systems
Stent Uniformity	The internal diameter of the stent must be ± 0.50mm from nominal labeled diameter after deployment to nominal pressure.	Pass	135 systems
Radial Strength	Minimum residual stent ID > 50% of the labeled stent nominal diameter after exposure to 63-88mmHg (minimum) pressure (REF).	Pass	45 stents
Test	**Acceptance Criteria**	**Bridge Extra**	**N**

		Support	
Fatigue Testing (Radial)	Withstand equivalent real time testing >400 million cycles	Pass @ >400 million cycles	864 welded crowns
Fatigue Testing (Respiratory)	The stent is not to exhibit a loss of radial integrity or experience any complete segment detachment during accelerated respiratory fatigue testing.	Pass	53 stents
Stent Recoil	5.0 – 6.0mm diameters: 0.033" diameter reduction 7.0mm diameters: 0.037" diameter reduction	Pass Pass	90 systems 45 systems
MRI	MRI compatible	Pass	7 stents
Stent Expansion	Stent is to exhibit no visible cracks or notches on any crown at 45X magnification (minimum) following a balloon burst test	Pass	30 stents
Dimensional Verification (stent)	Weld Length (0.009" min) Strut Thickness (0.0070"-0.0090") Strut Width (0.0085"-0.0121") Stent Length – 10mm (0.36"-0.42") Stent Length – 17mm (0.633"-0.693")	Pass	25 stents per attribute minimum
Maximum Pressure	Rated Burst Pressure: 12 ATM - 5.0, 6.0, & 7.0mm	Pass	105 systems
Stent Diameter vs. Pressure (stent compliance)	Stent Size Diameter (mm) Nominal Pressure 5.0 + 0.5mm 8 atm 6.0 + 0.5mm 8 atm 7.0 + 0.5mm 8 atm Note: Product labels are to be generated/supported by the compliance data.	Pass	18 systems

Test	Acceptance Criteria	Bridge Extra Support	N
Catheter Dimensions	Balloon Bond Length 1.0mm min. Tip Seal Length 1.0mm min. Tip ID 0.035" min. Tip Length 6.0mm max. Balloon Bond Gap 1.0mm min. Balloon Bond to Tack Bond Gap 10mm max. Tack Bond Length 3.0 mm min. Catheter Length 70-80cm (75cm system) 115-125cm (120cm system) Marker Band Spacing 10-13mm (-X10) 17-20mm (-X17)	Pass	135 systems
Bond Strength	Balloon bond (5.0mm diameter) >3.0 lbs. Balloon bond (6.0-7.0mm diameter) >4.5 lbs. Tack Bond >1.0 lbs. Luer Bond >4.0 lbs.	Pass	135 systems
Diameter and Profile	Balloon bond OD (5.0-6.0mm diameter) 0.080" max. Balloon bond OD (7.0mm diameter) 0.085" max. Tip OD (0.075" max.)	Pass	135 systems
Balloon Deflatibility	The catheter must release from the stent	Pass	10 systems
Balloon Deflation Time	13 seconds maximum	Pass	135 systems
Crossing Profile	≤ 0.086 inches	Pass	105 systems
Fatigue to Burst	20 cycles w/in stent @ 12 ATM (RBP)	Pass	120 systems

Animal studies

A single non-clinical research study was conducted to evaluate the acute deployment of the Bridge Extra Support stent in the renal vasculature of a single swine. The results indicate that the Bridge Extra Support can be successfully deployed.

10. Summary of Clinical Studies

The SOAR (Sub-Optimal Renal Angioplasty Results) Registry

Title: The SOAR (Sub-Optimal Renal Angioplasty Results) Registry with the Bridge Extra Support

Investigative Sites: Twenty-six investigative sites contributed patients to the SOAR Registry.

Purpose: The primary objective of this Registry was to evaluate the safety and effectiveness of the Bridge™ Extra Support renal stent and stent delivery system. The primary safety endpoints were the composite incidence of major adverse clinical events (MACE) at both 30-days post-procedure and again at 9-12 months post-procedure in patients treated with the study device. The primary effectiveness endpoint was the determination of the rate of restenosis at 9-12 months post procedure as evaluated by duplex ultrasound.

Study Design: This is a non-randomized, prospective, multi-center, consecutive study in patients determined as having a single *de novo* or restenotic lesion with sub-optimal or failed PTRA (Percutaneous Transluminal Renal Angioplasty) results.

Demographics: Patients enrolled in the SOAR Registry had a mean age of 69.0 ±9.8 years. There was 42.0% (79/188) male participation, and 41.5% (78/188) of the study population had a history of peripheral vascular disease. None of the patients had previously been on dialysis. All of the patients have a history of hypertension requiring medication. Refer to Table 1: Baseline Demographics and Clinical Characteristics.

Methods: Baseline angiographic and duplex ultrasound data, baseline data, and follow-up clinical data were collected on standardized case report forms by clinical investigators at the clinical sites. Clinical follow-up for all patients was performed at 1 month, 3 month, 6 month and 9-12 month (as office visits) post-procedure. Clinical follow-up at 9-12 months (± 14 days) was 93.6% (176/188) of patients. Clinical follow-up at 9-12 months includes but is not limited to: Quality of Life/Patient Contact follow-up, Ultrasounds Data follow-up, and Angiographic follow-up (if needed). The primary safety endpoints of the study were a composite endpoint of MACE at 30 days and at 9-12 months. The primary effectiveness endpoint was patency (restenosis) determined by Duplex ultrasound at 9-12 months. The secondary endpoint was Quality of Life improvement as determined by either a reduction in systolic and/or diastolic blood pressure, a reduction in the number or dosage of anti-hypertensive medications,

maintenance of normal renal function or no worsening of pre-procedure renal dysfunction or a decrease in associated medical symptoms (i.e., congestive heart failure, serum creatinine levels etc). Refer to Table 6: Summary of Quality of Life (QOL) Improvement Over Time. An independent Clinical Events Committee, adjudicated all of the major adverse clinical events. All endpoints were analyzed on an evaluable basis.

Results: The 30-day incidence of major adverse clinical events was 2.7% (5/185). The Kaplan-Meier estimate of freedom from MACE at 30 days was 97.9%. The 9-12 month incidence of major adverse clinical events was 16.0% (29/181). The Kaplan-Meier estimate of freedom from MACE at 9-12 months was 78.6%. Refer to Table 3: Principle Effectiveness and Safety Results.

The overall Quality of Life improvement, as defined above, was 94.0% (157/167) at the 9-12 month follow-up time period. The Blood Pressure Response indicated a total of 134/175 (76.6%) patients were either cured (7/175, 4.0%), improved (24/175, 13.7%), or had no significant change (103/175, 58.9%) in their blood pressure at 9-12 months. Based on the criteria for worsened blood pressure, 23.4% (41/175) of the patients were deemed "worsened" at their 9-12 month follow-up. The Antihypertensive Medication Changes indicated that there were a total of 51.1% (90/176) patients that would be categorized as having QOL improvement based on medication time alone – the number of medications and the dose of medications was reduced in 4.6% (8/176) of patients (2.8%, 5/176) of patients had either the number of medications or dose or medication reduced. A small number of patients (7.4%, 13/176) experienced either a reduction in number but increases in dose (4.5%, 8/176) or a decrease in dose but increase in number (2.8%, 5/176). The percentage of patients without a reduction in either the number of medications or the dose – no change – was 41.5% (73, 176). The Serum Creatinine Response indicated a total of 139/168 (82.7%) patients were either improved (8/168, 4.8%) or had no significant change (131/168, 82.7%), in their serum creatinine levels at 9-12 months. Based on the criteria for worsened serum creatinine, 17.3% (29/168) of the patients has levels that were deemed "worsened" at their 9-12 month follow-up.

Acute success was determined by angiographic evidence ≤30% residual stenosis and <5mm mean residual trans-stenotic gradient and classified according to 3 levels:

- Device success: Acute success using the Bridge Extra Support(s);
- Procedure success: Acute success using any percutaneous method (i.e., stent placement followed by another device);
- Clinical procedure success: Procedural success without the occurrence of any major adverse event prior to hospital discharge.

The device success rate was 92.4% (157/170) and both the procedure success and clinical success rate was 92.9% (158/170). Refer to Table 3: Principle Effectiveness and Safety Results.

- The 9-12 month incidence of restenosis based on duplex ultrasound evaluation was 16.8% (27/161).

The determination of success required both angiographic and trans-stenotic pressure gradient measurements. Of the 188 patients enrolled, 170 had both these measurements

recorded and therefore make up the denominator for the determination of these success criteria. The remaining 18 patients did not have pressure data recorded post-procedure, however, all had a $\leq$ 30% residual stenosis (angiographic success).

TABLE 1. Baseline Demographics and Clinical Characteristics

	All Patients Treated
Patient Characteristic	**(N=188 Patients)**
Age (yrs)	
Mean ± SD (N)	69.0 ± 9.8 (188)
Range (min, max)	42.0, 94.0
Gender	
Male	42.0% (79/188)
Female	58.0% (109/188)
Race	
White	91.0% (171/188)
Black	6.9% (13/188)
Hispanic	1.6% (3/188)
Asian	0.5% (1/188)
Other	0.0% (0/188)
Previous Dialysis Patient	0.0% (0/188)
History of:	
Peripheral Vascular Disease (PVD)	41.5% (78/188)
Gastrointestinal/Genitourinary (GI/GU) Bleeding	6.4% (12/188)
Cerebrovascular Accident (CVA) OR Transient-Ischemic Attack (TIA)	15.4% (29/188)
Diabetes Mellitus	23.4% (44/188)
Dyslipidemia Requiring Medication	65.4% (123/188)
Coronary Artery Bypass Graft(CABG)	35.3% (66/187)
Family History of Coronary Artery Disease (CAD)	61.7% (116/188)
Current Smoker	17.6% (33/188)
History of Hypertension Requiring Medication	100.0% (188/188)
Type of Anti-Hypertensive Medication*	
Agiotensin Converting Enzyme (ACE) Inhibitors	53.7% (101/188)
Beta Blockers	70.2% (132/188)
Calcium Channel Blocker	60.6% (114/188)
Vasodilator	28.7% (54/188)
Diuretic	51.3% (96/187)
Blood Pressure (mmHg)	
Systolic Mean ± SD (N)	160.0 ± 27.2 (188)
Range (min, max)	110, 256
Diastolic Mean ± SD (N)	77.3 ± 13.3 (188)
Range (min, max)	43, 112
Creatinine (mg/dl)	
Mean ± SD (N)	1.2 ± 0.3 (188)
Range (min, max)	0.4, 1.9
Target Artery	
Left Renal Artery	52.1% (98/188)
Right Renal Artery	47.9% (90/188)
Mean Follow-up Time (months)	
Mean ± SD (N)	10.7 ± 2.6 (188)
Range (min, max)	0.5, 24.9

Note: Numbers are mean +/- standard deviation (SD) or % (actual data / available sample size).
The counts and sample size number represents the actual data collected.
*Hypertension medications are not mutually exclusive.

TABLE 2. Baseline Lesion Characteristics and Hospital Length of Stay For 188 Lesions Treated in 188 Patients with Available Baseline QAA Data.

Lesion Characteristic (Angiographic Core Lab assessed)	
Pre-Procedure Reference Vessel Diameter (RVD in mm)	
Mean ± SD (N)	5.13 ± 0.92 (187)
Range (min, max)	3.11, 8.41
Pre-Procedure Minimal Lumen Diameter (MLD in mm)	
Mean ± SD (N)	2.01 ± 0.65 (184)
Range (min, max)	0.67, 4.37
Pre-Procedure Percent Diameter Stenosis (% DS)	
Mean ± SD (N)	60.8 ± 13.9 (187)
Range (min, max)	17, 99.0
Lesion Length (mm)	
Mean ± SD (N)	8.7 ± 3.9 (184)
Range (min, max)	2.3, 25.0
Calcification	
None	63.8% (120/188)
Mild	4.3% (8/188)
Moderate	8.0% (15/188)
Severe	0.5% (1/188)
Not Available	23.4% (44/188)
Eccentric Lesion	
No	49.5% (93/188)
Yes	50.0% (94/188)
Not Available	0.5% (1/188)
Percent Stenosis after PTRA % (Visual Estimate)	
Mean ± SD (N)	55.9 ± 15.5 (186)
Range (min, max)	0, 90
Baseline Duplex Ultrasound Assessment	
Peak Systolic Velocity (per Duplex Ultrasound) cm/sec	
Mean ± SD (N)	386.5 ± 149.0 (186)
Range (min, max)	103, 1100
Renal Aortic Ratio (RAR) (per Duplex Ultrasound)	
Mean ± SD (N)	5.2 ± 4.7 (185)
Range (min, max)	1.4, 61
Post-Procedure Hospital Length of Stay (days)	
Mean ± SD (N)	2.3 ± 1.5 (188)
Range (min, max)	1, 14

Note: Numbers are mean +/- standard deviation or % (actual data / available sample size).

TABLE 3. Principal Effectiveness and Safety Results
Bridge ™Extra Support
All Patients Treated

Effectiveness Measures	**% (# of events / total evaluable sample)[1] [CI]**
Acute Success: [2]	
Device Success	92.4% (157/170)
Procedure Success	92.9% (158/170)
Clinical Success	92.9% (158/170)
9-12 Month Incidence of Restenosis	16.8% (27/161)
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)	
Mean ± SD (N)	4.99 ± 0.78 (185)
Range (min, max)	3.20, 7.14
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)	
Mean ± SD (N)	2.5 ± 12.1 (185)
Range (min, max)	-38.0, 37.0
Target Lesion Revascularization/ Target Vessel Revascularization (TLR/TVR)-Free at 30 Months*	100%
Target Lesion Revascularization/ Target Vessel Revascularization (TLR/TVR)-Free at 9-12 Months*	90.9% [83.7%, 98.2%]
TVF-Free at 30 Days*	100%
TVF-Free at 9-12 Months*	90.9% [83.7%, 98.2%]
Death-Free at 30 Days*	99.5% [98.4%, 100%]
Death-Free at 9-12 Months*	97.2% [94.7%, 99.6%]
Major Adverse Clinical Events (MACE)-Free at 30 Days*	97.9% [95.8%, 99.9%]
MACE- Free at 9-12 Months*	78.6% [69.4%, 87.9%]
Secondary Measures:	
Summary of Blood Pressure (mmHg) Results	
Average Systolic	
Baseline	160.0 ± 27.2 (188)
30 Days	148.6 ± 21.9 (183)
9-12 months	146.5 ± 22.1 (175)
Average Diastolic	
Baseline	77.3 ± 13.3 (188)
30 days	76.4 ± 11.8 (183
9-12 months	75.9 ± 11.7 (175)
Summary of Antihypertensive Medications (9-12 months	
Reduction in both # of meds AND dose	4.68% (8/176)
Reduction in # of meds OR dose	46.6% (82/176)
Reduction in # of meds, but increase in dose	4.6% (8/176)
Reduction in dose, but increase in # of meds	2.8% (5/176)
No reduction in either # of meds of dose	41.5% (73/176)
Safety Measures and Other Clinical Events	**% (# of events/total evaluable sample)**
In-Hospital MACE	0.5% (1/188)
Out-of-Hospital MACE at 30 Days	2.7% (5/185)
Combined In and Out-of-Hospital MACE at 9-12 Months	16.0% (29/181)
Death	2.8% (5/181)
Target Lesion/Target Vessel Revascularization	6.6% (12/181)

Significant Embolic Events	6.6% (12/181)
Combined In and Out-of-Hospital MACE to 30 Days	
Abrupt Closure	0.5% (1/185)
Sub-acute Closure	0.0% (0/185)
Major Bleeding Complications	2.2% (4/185)
Major Vascular Complications	3.2% (6/185)
Cerebrovascular Accident (CVA) (peri-procedural)	0.0% (0/185)
Secondary Measures:	
Serum Creatinine: (mg/dl)	
Baseline - Mean ± SD (N)	1.2 ± 0.3 (188)
30 Day Improved	0.9 ± 0.4 (8/167)
30 Day No Change	1.18 ± 0.31 (138/167)
30 Day Worsened	1.5 ± 1.2 (21/167)
9-12 Month Improved	1.0 ± 0.3 (8/168)
9-12 Month No Change	1.2 ± 0.3 (131/168)
9-12 Month Worsened	1.6 ± 0.5 (29/168)

Note: Numbers are % (actual data / available sample size) or Mean ± SD. Confidence intervals are exact binomials.

[1] Denominators adjusted for available patient data for each parameter accordingly.

[2] Acute success was determined by angiographic evidence ≤30% residual stenosis and <5mm mean residual trans-stenotic pressure gradient in 170 patients and classified according to 3 levels:

Device success – Acute success using the Bridge™Extra Support stent(s).

Procedure success - Acute success using any percutaneous method, i.e., stent placement followed by another device.

Clinical procedural success - Procedural success without the occurrence of any major adverse clinical event prior to hospital discharge.

9-12 Month Incidence of Restenosis - Determined from the results of the duplex ultrasound scan as determined/defined by the presence of a peak systolic velocity of >180cm/sec and a corresponding renal/aortic ratio (RAR)≥ 3.5.

*Survival estimates by Kaplan-Meier method; Standard Error estimates by Peto formula:

TLR/TVR-free – No target lesion/vessel revascularization.

TVF-free – No target lesion/vessel revascularization, procedure related Q-wave MI, or death not clearly due to a non-target lesion/vessel.

MACE-free at 30-days – No death, procedure related Q wave MI, TLR/TVR, or significant embolic event.

MACE-free at 9-12 months – No death, TLR/TVR, or significant embolic event.

In-Hospital MACE – Death, procedure-related Q-wave MI, target lesion/vessel revascularization (TLR/TVR), or significant embolic events (defined as kidney/bowel infarct, gangrenous/ulcerated foot or decrease in renal function as determined by creatinine levels) prior to discharge as determined by the independent Clinical Events Committee (CEC).

Out-of-Hospital MACE at 30 days – Death, procedure-related Q-wave MI, target lesion/vessel revascularization (TLR/TVR), or significant embolic events from hospital discharge through 30 days, as determined by the CEC.

Out-of-Hospital MACE at 9-12 months – Death, target lesion/vessel revascularization (TLR/TVR), or significant embolic events from hospital discharge through 9-12 months, as determined by the CEC

Abrupt Closure - closure occurring within 24 hours of the procedure

Sub-acute Closure - closure between 24 hours and 30 days

Major bleeding complications - A procedural related vascular access site/bleeding event that requires a transfusion of blood or blood products or a transfusion required during the hospitalization for the stent implant if not clearly procedure related.

Major vascular complications - Any procedure related event such as hematoma at access site >4 cm, retroperitoneal bleed, pseudoaneurysm, arteriovenous fistula, peripheral ischemia/nerve injury, unexplained leg pain/Claudication/numbness, procedure related

gastrointestinal/genitourinary bleeding or vascular access site complication requiring surgical repair.

Cerebrovascular Accident (CVA) – Occurrence of any peri-procedural ischemic or hemorrhagic neurological event, as determined by the independent Clinical Events Committee.

Serum Creatine-

"Improved" if the baseline was "Normal" and the follow-up value was reducted by 25% of the baseline value or if the baseline was "Above normal" and the follow-up value was reducted by 20%.

"Worsened" if the baseline as "Normal" and the follow-up value was increased by 25% of the baseline value or if the baseline was "Above normal" and the follow-up value was increased by 20%.

"Normal and "Above normal" refer to the baseline creatinine values. A value is considered "Normal" if it is <1.4mg/dl.

"Above normal"> 1.5mg/dl.

TABLE 4. Major Adverse Events – In-Hospital and Out of Hospital and Combined to 30 Days

All Patients Treated

Description of Event	**% (# of events / total evaluable sample)***
In-Hospital Complications	
MACE (Death, procedure-related Q-wave MI, target lesion/vessel revascularization, or significant embolic events)	0.5% (1/188)
Death	0.0% (0/188)
Procedure-related Q-wave MI	0.5% (1/188)
Target Lesion/Vessel Revascularization	0.0% (0/188)
Significant Embolic Events	0.0% (0/188)
Abrupt Closure	0.5% (1/188)
Subacute Closure	0.0% (0/188)
Major Bleeding Complications	2.1% (4/188)
Major Vascular Complications	2.1% (4/188)
Cerebrovascular Accident (CVA) (peri-procedural)	0.0% (0/188)
Out of Hospital Complications (to 30 days)	**% (# of events / total evaluable sample) [1]**
MACE (Death, procedure-related Q-wave MI, target lesion/vessel revascularization, or significant embolic events)	2.7% (5/185)
Death	0.5% (1/185)
Procedure-related Q-wave MI	0.0% (0/185)
Target Lesion/Vessel Revascularization	0.0% (0/185)
Significant Embolic Events	2.2% (4/185)
kidney/bowel infarct	0.0% (0/185)
gangrenous/ulcerated foot	0.0% (0/185)
decrease in renal function (>50% increase in creatinine levels)	2.1% (4/185)
Abrupt Closure	0.0% (0/185)
Subacute Closure	0.0% (0/185)
Major Bleeding Complications	0.0% (0/185)
Major Vascular Complications	1.1% (2/185)
Cerebrovascular Accident (CVA) (peri-procedural)	0.0% (0/185)

Combined In- and Out of Hospital Complications (to 30 days)	% (# of events / total evaluable sample) [1]
MACE (Death, procedure-related Q-wave MI, target lesion/vessel revascularization, or significant embolic events)	3.2% (6/185)
Death	0.5% (1/185)
Procedure-related Q-wave MI	0.5% (1/185)
Target Lesion/Vessel Revascularization	0.0% (0/185)
Significant Embolic Events	2.2% (4/185)
kidney/bowel infarct	0.0% (0/185)
gangrenous/ulcerated foot	0.0% (0/185)
decrease in renal function (>50% increase in creatinine levels)	2.2% (4/185)
Abrupt Closure	0.5% (1/185)
Subacute Closure	0.0% (0/185)
Major Bleeding Complications	2.2% (4/185)
Major Vascular Complications	3.2% (6/185)
Cerebrovascular Accident (CVA) (peri-procedural)	0.0% (0/185)

*Note: Numbers are % (actual data / available sample size).
Confidence intervals are exact binomials.

[1] Excludes one patient who withdrew their consent prior to 30 days and two patients without 30-day data.

Clinical Follow-up Available at 30 days (± 7 days)	97.9% (184/188)** ** Follow-up not available for one patient who withdrew consent, two patients without 30-day data, and 1 patient death.

TABLE 5. Major Adverse Clinical Events (MACE) – Combined In- and Out of Hospital to 9-12 Months

All Patients Evaluated (N=188 Patients)

Description of Event	% (# of events / total evaluable sample) * [1]
Combined In- and Out of Hospital MACE to 9-12 months	
Mace (Death, target lesion/vessel revascularization, or significant embolic events)	16.0% (29/181)
Death	2.8% (5/181)
Target Lesion/Vessel Revascularization	6.6% (12/181)
Significant Embolic Events	6.6% (12/181)
kidney/bowel infarct	0.5% (1/181)
Gangrenous/ulcerated foot	0.0% (0/181)
Decrease in renal function (>50% increase in creatinine levels)	6.1% (11/181)

% Number are counts (patients or events)/sample size
[1] Excludes seven patients who were Lost to Follow-up or Withdrew their consent at 9-12 months.

Clinical Follow-up Available at 9-12 Months (± 14 days)	93.6% (176/188)** **7 patients excluded who were lost to follow-up or Withdrew their consent at 9-12 months. 5 additional patients patients excluded due to death.

TABLE 6. Summary of Quality of Life (QOL) Improvement Over Time All Patients Evaluated

	30 Days	3 Months	6 Months	9-12 months
Improvement in QOL	94.0% (157/167)	98.2% (163/166)	97.0% (160/165)	94.0% (157/167)

	9-12 Month Follow-up Time Period % (# of events / total evaluable sample)
Blood Pressure Response:	**76.6% (134/175**
Cured	4.0% (7/175)
Improved	13.7% (24/175)
No significant Change	58.9% (103/175)
Worsened	23.4% (41/175)
Antihypertensive Medication Changes:	**51.1% (90/176)**
Reduction	4.6% (8/176)
# of medications or dose reduced	2.8% (5/176)
Reduction in # of medications but increase in dose	4.5% (8/176)
Decrease in dose but increase in # of medications	2.8% (5/176)
No change	41.5% (73/176)
Serum Creatinine:	**82.7% (139/168)**
Improved	4.8% (8/168)
No significant change	82.7% (131/168)
Worsened	17.3% (29/168)

Note: Numbers are % (actual data / available sample size).

11. Conclusions Drawn from Studies

The *in vitro* and *in vivo* non-clinical laboratory studies, together with clinical investigations, provide valid scientific evidence and reasonable assurance that the Bridge Extra Support is safe and effective for its intended use.

The safety and effectiveness of the Bridge™ Extra Support has been demonstrated through determination of the acute procedure success and Major Adverse Clinical Events (MACE) as follows:

- Acute procedural success of 92.9%.

- Out-of-Hospital at 30 days MACE (death, procedure-related Q-wave MI, target lesion/vessel revascularization (TLR/TVR), or significant embolic events) rate of 2.7%.
- Out-of-Hospital MACE at 9-12 months MACE (death, target lesion/vessel revascularization (TLR/TVR), or significant embolic events) rate of 16.0%.

The 9-12 month incidence of restenosis based on duplex ultrasound evaluation was 16.8% (27/161) and
the overall Quality of Life improvement, as defined above, was 94.0% (157/167) at the 9-12 month follow-up time period.

The clinical investigation results demonstrate that the Bridge™ Extra Support, when used in the treatment of single *de novo* lesions, able to be covered with a single stent, with sub-optimal or failed PTRA (Percutaneous Transluminal Renal Angioplasty) in renal arteries with reference vessel diameters ranging from 5.0 mm to 7.0 mm, does not pose any additional risk to the patient population treated.

12. Panel Recommendation

In accordance with provisions of section 515(c)(2)of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory Systems Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

13. CDRH Decision

Based upon a review of the data contained in the PMA, CDRH determined there is reasonable assurance that the device is safe and effective for it's intended use. Furthermore, the applicant agreed to conduct a post approval study in order to gather long-term safety and effectiveness data. Subjects in the SOAR trial will be followed for 3 years and the labeling will be updated with the study results.

An FDA inspection of the applicants manufacturing facilities determined that the facilities were in compliance with the quality system regulations (21 CFR 820).

The FDA issued an approval order on: December 18, 2002

14. Approval Specifications

IFU (see labeling)

Hazards to health from use of the device: See Indications, Contraindications, Warnings and precautions and Adverse Events in the labeling.

Post approval requirements and restrictions: See Approval Order.