SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

Device Generic Name: Intravascular Stent with Delivery System

Device Trade Name: Express™ Coronary Stent System
Express 2™ Monorail™ Coronary Stent System
Express 2™ Over The Wire Coronary Stent System

Applicants name and address: Boston Scientific Scimed, Inc.
One Scimed Place
Maple Grove, MN 55311

PMA Number: P020009

Date of Panel Recommendations: None

Date of Notice of Approval To Applicant: September 11, 2002

II. INDICATIONS FOR USE

The Express/Express 2 Monorail/Express 2 OTW are indicated for improving coronary luminal diameter in the following:

- Patients with symptomatic ischemic disease associated with stenotic lesions in native coronary arteries (length $\leq$ 18 mm) with a reference vessel diameter of 3.0 to 5.0 mm.
- Treatment of abrupt or threatened abrupt closure (AC/TAC) in patients with failed interventional therapy in lesions in native coronary arteries of 2.25 to 5.0 mm (inclusive) in diameter and $\leq$ 30mm long.

Long-term outcome (beyond 6 months) for this permanent implant is unknown at present.

III. CONTRAINDICATIONS

The Express/Express 2 Monorail/Express 2 OTW is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.
- Patients with known allergies to stainless steel.

IV. WARNINGS AND PRECAUTIONS

Please refer to the device labeling for a list of warnings and precautions.

V. DEVICE DESCRIPTION

The Boston Scientific Scimed® Express™ Monorail and Express 2™ Monorail and Over-the-Wire Coronary Stent Systems (Express, Express 2 MR, and Express 2 OTW Systems) consist of a balloon expandable stent, pre-mounted on a high-pressure delivery catheter and are used in the treatment of coronary artery disease. The Express Coronary Stent System consists of the Express stent pre-mounted on a BSC Elite Monorail delivery catheter. The Express 2 Monorail and Over-the-Wire Coronary Stent Systems consist of the Express stent pre-mounted on a BSC Maverick™ Monorail or Over-the-Wire delivery catheter, respectively.

The same Express Stent is used on the Express, Express 2 MR and Express 2 OTW catheter systems. The Express Stent is laser cut from a 316L stainless steel tube into a specific geometric pattern. The pattern consists of a multitude of radially expandable elements with varying amplitude, which are interconnected by longitudinally oriented elements. The interconnected elements are offset along the length of the stent in order to maintain a balance of longitudinal forces along the stent.

Table 1. Stent Specifications

Table 1					
Express and Express 2 MR and OTW System Characteristics					
Stent Diameter	**Nominal Pressure**	**Rated Burst Pressure**	**Express Monorail Guide Compatibility**	**Express2 Monorail Guide Compatibility**	**Express2 OTW Guide Compatibility**
2.25 mm	9 Atm	18 Atm	5 F (.058")	5 F (.058")	6F (.066")
2.50 mm	9 Atm	18 Atm	5 F (.058")	5 F (.058")	6F (.066")
2.75 mm	9 Atm	18 Atm	5 F (.058")	5 F (.058")	6F (.066")
3.00 mm	9 Atm	18 Atm	5 F (.058")	5 F (.058")	6F (.066")
3.50 mm	9 Atm	18 Atm	5 F (.058")	5 F (.058")	6F (.066")
4.00 mm	9 Atm	18 Atm	5 F (.058")	5 F (.058")	6F (.066")
4.50 mm	9 Atm	16 Atm	6F (.066")	6F (.066")	6F (.066")
5.00 mm	9 Atm	16 Atm	6F (.066")	6F (.066")	6F (.066")

The Express™/Express™ 2 Monorail/Express™ 2 OTW are each available in 50 device models in combinations of both small and large vessel Express™ Stents, with stent lengths of 8, 12, 16, 20, 24, 28 and 32 mm and balloon diameters of 2.25, 2.5, 2.75, 3.0, 3.5, 4.0, 4.5, and 5.0 mm, as shown in the matrix below. The stent is centered on a high pressure balloon between two radiopaque markerbands to aid in positioning the system during the procedure.

The balloon extends approximately 0.3 mm beyond the stent ends to ensure full expansion of the stent during deployment while minimizing the amount of balloon outside the stent region.

Express and Express 2 MR and OTW System Product Matrix								
		Stent Length						
		8 mm	12 mm	16 mm	20 mm	24 mm	28mm	32 mm
Stent Diameter	2.25 mm	X	X	X	X	X		
	2.50 mm	X	X	X	X	X		
	2.75 mm	X	X	X	X	X	X	X
	3.00 mm	X	X	X	X	X	X	X
	3.50 mm	X	X	X	X	X	X	X
		Designated Stent Model Separation						
	4.00 mm	X	X	X	X	X	X	X
	4.50 mm		X	X	X	X	X	X
	5.00 mm		X	X	X	X	X	X

The distal section of the catheter is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, which results in deployment and expansion of the stent. The inner lumen permits the use of guide wires (< 0.014 inches) to facilitate advancement of the catheter through the vasculature and lesion to be stented. The wire lumen has a port for use with appropriate coronary guide wires. The catheter includes a tapered tip to facilitate the advancement of the catheter through the stenosis.

VI. ALTERNATIVE PRACTICE AND PROCEDURES

Alternative treatments of coronary atherosclerotic disease include diet, medication (e.g. thrombolysis), atherectomy, balloon angioplasty, coronary bypass (CABG) surgery or stenting with commercially available stents.

VII. MARKETING HISTORY

The Express Coronary Stent System is registered for sale in the following countries.

Commercial Approval of Express Coronary Stent System			
Argentina	Djibouti	Kenya	Poland
Albania	Dominican Rep.	Korea	Portugal
Algeria	Dutch Antilles	Kuwait	Qatar
Aruba	Ecuador	Latvia	Romania
Austria	Egypt	Lebanon	Saudi Arabia
Australia	El Salvador	Liechtenstein	S. Africa
Bahrain	England	Lithuania	Singapore
Belize	Estonia	Luxemburg	Slovenia
Bermuda	Finland	Macedonia	Sri Lanka
Barbados	France	Malaysia	Sweden
Belgium	Germany	Malta	Switzerland
Bermuda	Greece	Martinique	Syria
Bosnia	Guatemala	Mexico	Taiwan
Brazil	Haiti	Moldavia	Trinidad
Bulgaria	Honduras	Morocco	Thailand
Canada	Hong Kong	Netherlands	Tobago
Chile	Hungary	Nicaragua	Tunisia
China	Iceland	Norway	Turkey
Columbia	India	New Zealand	Ukraine
Costa Rica	Indonesia	Pakistan	Uruguay
Croatia	Ireland	Panama	United Arab Em.
Cyprus	Italy	Paraguay	Venezuela
Czech Rep.	Jamaica	Peru	Vietnam
Denmark	Jordan	Philippines	Yemen

The Express Coronary Stent System was granted approval by Boston Scientific's notified body (TUV Rheinland) to permit CE marking June 18, 2001. BSC began marketing the product internationally following approval in September 2001. The Express 2 Monorail and Over-the-Wire Coronary Stent Systems have not yet been marketed in any country.

The Express Coronary Stent System has not been withdrawn in any country due to reasons related to safety and effectiveness of the device.

VIII. SUMMARY OF NON-CLINICAL STUDIES

A. Biocompatibility

1. Express Stent and Express Monorail Delivery Catheter

The following testing as recommended in the International Standard EN/ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" for this category of devices was carried out on finished Express systems. All testing was

conducted on finished, premounted stent systems except the Subchronic Toxicity Test and the 30-day Implant Test, which were carried out on the stent only.

Test Performed	Test Device Type	Results
Cytotoxicity	Stent Loaded Delivery System	**Pass**
Sensitization	Stent Loaded Delivery System	**Pass**
Intracutaneous Toxicity	Stent Loaded Delivery System	**Pass**
Systemic Toxicity	Stent Loaded Delivery System	**Pass**
Subchronic Toxicity	Stent Alone	**Pass**
Implantation	Stent Alone	**Pass**
In-Vitro Hemocompatibility Assay	Stent Loaded Delivery System	**Pass**
Direct Hemolysis Aution	Stent Loaded Delivery System	**Pass**
Modified Lee and White Coagulation Thrombogenicity	Stent Loaded Delivery System	**Pass**
Pyrogenicity,Rabbit Blood, Aution Method	Stent Loaded Delivery System	**Pass**
Pyrogenicity LAL, Scimed	Stent Loaded Delivery System	**Pass**

It should be noted that Genotoxicity, Chronic Toxicity, Carcinogenicity and Immunotoxicity testing are not being carried out. These tests are traditionally only carried out on implanted materials. Because of the vast experience of using 316L stainless steel as an implant material, specifically for stents, this testing is not deemed necessary.

2. Express™ 2 Monorail Delivery Catheter

The Express 2 Monorail Stent Delivery Catheter is a combination of the same materials in the same relative proportions, manufactured in the same location and using essentially the same manufacturing methods used for the established Scimed Maverick Monorail balloon catheter (P860019/S160) and the Scimed Express Monorail Coronary Stent System. The following table outlines testing that was completed on the Maverick Monorail, Express Monorail, and Express 2 Monorail products.

Test Performed	Test Device Type	Results
Cytotoxicity MEM Elution	Maverick Monorail Catheter Express Monorail Delivery System + stent	**Pass** **Pass**
Systemic Toxicity	Maverick Monorail Catheter Express Monorail Delivery System + stent	**Pass** **Pass**
Material Mediated Rabbit Pyrogenicity	Express 2 Monorail Delivery System	**Pass**
Intracutaneous Injection	Maverick Monorail Catheter Express Monorail Delivery System + stent	**Pass** **Pass**
Skin Sensitization Kligman	Maverick Monorail Catheter Express Monorail Delivery System + stent	**Pass** **Pass**
Direct Hemolysis	Maverick Monorail Catheter Express Monorail Delivery System + stent	**Pass** **Pass**
In Vitro Hemocompatibility Assay	Express 2 Monorail Delivery System	**Pass**
Lee and White Coagulation	Express 2 Monorail Delivery System	**Pass**
USP Physicochemical Test for Plastics	Maverick Monorail Catheter	**Pass**
14 Day Repeat Dose Intravenous Toxicity	Express Bare Stent	**Pass**
Muscle Implant, 14 and 30 Days	Express Bare Stent	**Pass**

3. Express™ 2 Over-the-Wire Delivery Catheter

The Express 2 Over-the-Wire Stent Delivery Catheter is a combination of the same materials in the same relative proportions, manufactured in the same location and using essentially the same manufacturing methods used for the established Scimed Maverick Over-the-Wire balloon catheter (P860019/S162) and the Scimed Express Monorail Coronary Stent System. The following table outlines testing that was completed on the Maverick OTW, Express Monorail, and Express 2 OTW products.

Test Performed	Test Device	Results
Cytotoxicity MEM Elution	Maverick OTW Catheter Express Delivery System + stent	**Pass** **Pass**
Systemic Toxicity	Maverick OTW Catheter Express Delivery System + stent	**Pass** **Pass**
Material Mediated Rabbit Pyrogenicity	Express 2 OTW Delivery System	**Pass**
Intracutaneous Injection	Maverick OTW Catheter Express Delivery System + stent	**Pass** **Pass**
Skin Sensitization Kligman	Maverick OTW Catheter Express Delivery System + stent	**Pass** **Pass**
Direct Hemolysis	Maverick OTW Catheter Express Delivery System + stent	**Pass** **Pass**
In Vitro Hemocompatibility Assay	Express 2 OTW Delivery System	**Pass**
Lee and White Coagulation	Express 2 OTW Delivery System	**Pass**
USP Physicochemical Test for	Maverick OTW Catheter	**Pass**

Plastics		
14 Day Repeat Dose Intravenous Toxicity	Express Bare Stent	**Pass**
Muscle Implant, 14 and 30 Days	Express Bare Stent	**Pass**

B. Physical Testing

In vitro bench testing to support the Express/Express 2 Monorail/Express 2 OTW Coronary Stent System was conducted, as applicable, in accordance with the FDA Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices, May, 1994.

Part 1 Express Stent

The following is the *in vitro* testing to support the Express Stent as used in the Express/Express 2 Monorail/Express 2 OTW Coronary Stent System. Testing is representative of both the small and large vessel stents in diameters of 2.25 to 3.5 mm and 4.0 to 5.0 mm, respectively. Stent length and diameter are not a factor in material specification conformance testing.

1) Stent Material Specification Conformance Testing

a) Material Analysis

The Express stent raw material was chemically analyzed and found to conform in both chemical analysis and the inclusion/impurity content as provided in ASTM-F 139, "Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)".

b) Surface Contamination

The Express stent was examined via SEM at 500X and 2000X to detect evidence of surface contamination or impurities on the stent material not removed by cleaning processes. Results of SEM evaluation showed no evidence of contamination above the specified limits.

c) Mechanical Properties: Tensile Strength and Elongation

Tensile strength and elongation testing was performed on the stent raw material to determine the yield strength and percent elongation of the Express stent material. The tensile strength was between 90.5 and 93.8 ksi and the elongation was between 45 and 49%. The yield stength and elongation of the Express stent met the product specifications.

d) Cyclic Potentiodynamic Polarization

Testing was conducted in accordance with ASTM-G 61, "Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements for Localized Corrosion Susceptibility of Iron-, Nickel-, or Cobalt-Based Alloys", to demonstrate that finished stents exhibit corrosion and repassivation characteristics comparable to marketed stents for 316L type stainless steel implant material. The results indicated that the corrosion resistance of the device met product specifications.

2) **Stent Integrity Testing**

a) **Metal to Artery Percentage**

The metal surface coverage as a function of stent diameter was calculated by dividing the total vessel contact metal surface area of the stent structure by the surface area of the vessel at any given stent/vessel diameter. Metal to artery percentage ratios were calculated from 11.3% - 19.1 % for 2.25 mm to 5.0 mm stents to capture the metal to artery percentage across the entire range of target vessel size recommended in the device labeling.

b) **Length Changes Upon Expansion: Stent Foreshortening**

Ten (10) Express Stents of each of the following stent lengths: 8, 16, 20 and 32 mm were tested at the largest labeled diameter (3.5mm) for the 2.25-3.5mm stents, and 12, 16, 20 and 32mm were tested at the largest labeled diameter (5.0mm) for the 4.0-5.0mm stents. Measurements of the stent constrained length were made and recorded for each stent at baseline and after inflation to 9 atm. The catheter was deflated and the length measurements repeated. Values ranged from 0.02 to 0.90mm. All stents met the product specification.

c) **Stent Expansion Uniformity**

Testing was conducted to determine the uniformity of stent expansion along the stent length, fifteen (15) each of 2.25/16mm and 4.0/16mm stent sizes were tested. Units were inflated to 9 atm, then measurements were taken at 3 points along the stent length after inflation. Measurements were averaged and compared to baseline measurements. All Express stents met the uniformity expansion specification of $\pm$ 5% of their diameter at their nominal diameter with a range of 0.58 % - 2.08 %.

d) **Stent Recoil**

Testing was conducted to quantify the amount of elastic recoil for the Express Stent and correlate this parameter to the recommended sizing procedure. Fifteen (15) Express Stents of each 2.25/16mm, and 4.0/16mm stent sizes were tested. The system was inflated to nominal diameter and measurements were taken of the stent diameter at 3 locations along the stent. The system was then deflated and the same measurements taken. Percent recoil ranged from 1.44% – 3.82 %. Results indicated that the Express stent met its product specification.

e) **Stent Conformability Testing**

Testing was conducted to determine the conformability (axial flexibility) of the stent in its expanded state by determining the pure bending moment of the stent. Fifteen (15) of the 3.0/16mm stents and 10 each of the 3.5/16mm and 5.0/16mm stents were tested. The amount of force is measured which is required to create a curvature of 0.04 radian/mm for a stent expanded to 3.0mm. Larger stents were

required to create a curvature that was less than other currently marketed stents. The mean force at 3.0mm ranged from 0.32-0.45 N*mm, demonstrating that the Express Stent is conformable and met its product specification. Larger stents were required to be less than other marketed stents. All stents met their requirements.

f) Compression Resistance/Radial Hoop Strength

Testing was conducted to determine the radial resistance of the Express Stent to external compression. Fifteen (15) Express Stents of each 2.25/16 mm and 4.0/16 mm stent sizes were tested. All stents were expanded to nominal stent diameter. The stents were then placed in the base U-block of the compression tester. Loading forces were obtained at the nominal diameter of the U-block used (after 0.5mm of radial stent compression from the nominal stent diameter). Compression resistance ranged from 0.1042 - 0.1510 lbs/mm. All Express stents met the compression resistance requirements.

g) Stent Expansion and Safety Margin

Testing was conducted to determine whether the deformation experienced by the stent undergoing expansion above the maximum rated diameter gives rise to stent fracture. Fifteen (15) each of the 3.5/16mm and 5.0/16mm design were tested. The 2.25-3.5mm stent was expanded to 4.25mm, and the 4.0 to 5.0mm stent was expanded to 5.75mm. No stents exhibited any fractures or structural damage when visually examined at 20X magnification following over-expansion.

h) Magnetic Resonance Imaging

The following statement is supplied in the Instruction For Use, "Do not perform Magnetic Resonance Imaging (MRI) scan on patient's post-stent implantation until the stent has been completely endothelialized (eight weeks) to minimize the potential for migration. The stent may cause artifacts in MRI scans due to distortion of the magnetic field."

i) Stent Dimensional Verification

Testing was conducted to measure and optically inspect the stent to document that dimensional specifications do not deviate from the product specification. Ten (10) Express Stents of each design (2.25-3.5 and 4.0-5.0) were tested. In addition, shortest and longest (8 and 32 mm) lengths of each design were also tested to show that adequate manufacturing controls cover the range of stent sizes. Stents were not mounted on their delivery catheters or sterilized. Each stent was measured with the FineScan stent measurement system. All Express Stents tested met their specified requirements for dimensional criteria indicating that the stent dimensions are adequately controlled during manufacturing.

j) Finite Element Analysis

An in-depth analysis of the Express Stent was conducted to ensure that the implant conditions to which the stent will be subjected would not result in failure due to fatigue. The FEA evaluated the structural integrity of the Express stent when the stent was subjected to the expected load conditions generated in coronary arteries. The analysis took into account static and fatigue loading at nominal balloon expansion. The results were compared to the measured strain at breakpoint. The strain vs. extension analysis and the Goodman analysis showed that local deformation did not exceed the breakage strain specification. The Goodman analysis showed no fatigue failure will occur over the 400 million cycles of loading and is within specification.

k) Ten Year Accelerated Pulsatile Fatigue Testing

Accelerated *in vitro* stent testing of approximately 10 years (400 million cycles) equivalent real time was conducted to ensure that the Express stent, when expanded to its largest intended diameters, will not show fatigue failure during simulated 10 year time span testing. The stents were expanded and then mounted on the inside of an appropriate sized silicone rubber tube. The stents were dynamically cycled over simulated vessel conditions for 400 million cycles. Visual inspection was carried out between 50X-70X using optical microscopy. No signs of cracking, breaking or splitting were detected. Additionally, four stents from each group were randomly analyzed using SEM. All tested stents were free from fatigue induced surface defects such as strut cracks and strut breakage. The Express stent met the 10 year accelerated fatigue resistance requirement of the product specification.

l) Stent Radiopacity

Testing was conducted to determine radiopacity of the Express Stent relative to other currently marketed stents. The stents were deployed in air to their nominal diameter using the manufacturer's instructions for use. Upon deployment the stents were placed on two, 1mm thick copper sheets. The copper sheets were used as a phantom to simulate the view during clinical use under fluoroscopy. The stents were then viewed using a fluoooscopy. The radiopacity of the Express Stent is comparable to other marketed stents.

Part 2 Premounted System Testing

The following *in vitro* testing is provided for the Express/Express 2 MR/Express 2 OTW Coronary Stent System to evaluate performance characteristics and safety of the stent/catheter system. All test results indicated that the devices/samples met or exceeded design specifications.

1. **Express Coronary Stent System Testing**

   a) **Balloon in a Stent Burst, Balloon Bonds and Inflation Lumen Integrity Testing**
   As per the guidance recommended by the FDA, a minimum of 15 samples of the Express Coronary Stent System of the smallest/shortest (2.25/8mm), largest/shortest (5.0/12mm) and the longest lengths of every diameter balloon/stent size were tested to burst. All other sizes were also tested and required to meet rated burst requirements. All stent systems met rated burst pressure. In addition the stent/balloon burst results show statistically that with 95% confidence, 99.9% of the Express Coronary Stent System will not experience balloon, shaft, or proximal/distal seal loss of integrity at or below the maximum recommended rated balloon burst pressure.

   b) **Stent Nominal Sizing, Distension and Compliance Labeling**
   Testing was conducted to verify that the distention characteristics of the Express Coronary Stent System meet the labeled specifications. A minimum of forty-five (45) complete Express systems of each diameter and varying lengths were tested to verify the typical post deployment stent ID compliance data. In addition, a minimum of 5 units of all sizes were tested to verify average diameters at nominal (9 atm). The stent sizing results verify that the Express Coronary Stent Systems meet the labeled compliance values.

   c) **Stent Deployment Testing**
   Testing was performed on the Express Coronary Stent System to determine the stent deployment pressure and the ability of the balloon to be withdrawn from the stent. A minimum of 45 samples of each diameter (5 of every length and diameter) of the Express Coronary Stent System were tested. All Express Coronary Stent Systems met the labeled deployment specification of $\leq$132 psi (9 atm).

   d) **Balloon Inflation and Deflation Testing**
   Fifteen (15) each of the following Express Coronary Stent Systems were tested for inflation/deflation: 4.0/20 mm, 4.0/32 mm, 5.0/32 mm. Inflation times ranged from 2.0 – 3.2 seconds, while deflation times ranged from 9.3 – 12.7 seconds. All samples met the product specification.

   e) **Repeat Balloon Inflation**
   Thirty samples each of the 2.25/8mm (smallest/shortest), 5.0/12mm (largest/shortest), 2.25/24mm (smallest/longest) and the 5.0/32mm (largest/longest) Express delivery systems were required to complete 20 pressurization cycles to Rated Burst Pressure without failure. The stent/balloon burst results show statistically that, with 95% confidence, 90% of the catheters will not experience balloon, shaft, or proximal/distal seal loss of integrity at or below the maximum recommended rated balloon burst pressure.

f) Stent/Balloon Crossing Profile

A minimum of five (5) Express Coronary Stent Systems for the longest stent length of every diameter were tested to determine the deflated stent/balloon profile. Average deflated profiles of the delivery systems ranged from 0.39 – 0.58 inches. All samples met the product specification.

g) Shaft Diameters

Fifteen (15) systems each of the 4.0/20mm, 4.0/32mm and 5.0/32mm were tested to determine the proximal shaft, distal shaft and distal tip diameters for the Express Coronary Stent Systems. The Express Coronary Stent Systems proximal shaft, distal shaft, and distal tip diameters were comparable to currently marketed stent delivery systems.

h) Pre- and Post-Deployment Catheter Withdrawal Into a Guide & Deflatibility Testing

Testing was carried out to verify that the Express Coronary Stent System can be safely withdrawn back into the recommended guide catheter sizes both before and after stent deployment and the ability of the balloon to be withdrawn from the stent. Fifteen (15) each of the 4.0/32 and 5.0/32 mm systems were tested. Pre-deployment forces ranged from 0.06 – 0.26 lbs and post-deployment forces ranged from 0.51 – 0.82 lbs indicating that Express Coronary Stent Systems can be easily withdrawn back into the recommended guide catheter prior to and after stent deployment. All samples met the product specification.

i) Stent Securement Force Testing

Testing was conducted to assess the force required to displace a crimped stent from its catheter. A minimum of fifteen (15) samples each of the smallest and largest diameter, and the longest and shortest stent lengths for each type stent (2.25-3.5mm, and 4.0-5.0mm) were tested. In addition, seventeen (17) 3.0/9mm NIR ON™ Ranger stents were tested using the same protocol as a point of reference. All stent systems met the stent securement specification of $\geq$ 0.2lbs. Stent securement to the specification was demonstrated with 95% confidence that 99.7% of the Express Coronary Stent Systems will not be dislodged from the balloon. In addition the Express Stents exhibit stent securement comparable to the NIR ON™ Ranger stent.

j) System Device Tracking

Testing was conducted to demonstrate that the tracking force of the Express Coronary Stent System through a simulated artery is comparable to currently marketed devices. Ten (10) 3.0/16mm Express and six (6) 3.0/18mm Guidant Tri-Star stent systems were loaded over a 0.014" guide wire and inserted into a 6 French (Wise Guide - 0.066" ID) guide catheter and simulated artery until the stent/balloon fully exited the distal end of the guide catheter. The guide wire was

pushed distal to the distal end of the simulated artery and securely fastened. The catheter was then advanced through the artery while measuring the peak force. The Express average peak track force ranged from 0.150-0.227 lbs. While the Guidant Tri-Star force ranged from 0.172-0.237 lbs., demonstrating that the Express Coronary Stent System tracking force is comparable to a currently marketed device.

k) Full Unit Tensile Test

A minimum of fifteen (15) each of the 4.0/20mm, 4.0/32mm, and 5.0/32mm Express Coronary Stent Systems were tested to determine the tensile strength of the Express delivery catheter. The average tensile strength at failure was 2.08, 2.35, and 2.33 lbs. respectively. All Express Coronary Stent Systems exceeded the minimum catheter tensile strength specification of 1.40 lbs.

l) Packaging

Testing was conducted to determine the break free force required to dislodge the Express manifold from its protective hoop and to determine the force required to remove the Express stent delivery system from its protective hoop. All Express delivery systems were able to be removed from their protective hoop without difficulty and without any damage imparted to any of the representative systems. All test units met their required specifications.

2. Express 2 MR and OTW Coronary Stent System Testing

Because of the large number of similarities between the Monorail and Over The Wire Express 2 delivery catheters (the distal ends are identical, see Device Description), testing represents both models.

a) Balloon in a Stent Burst, Balloon Bonds and Inflation Lumen Integrity Testing

As per the guidance recommended by the FDA a minimum of 15 samples of the Express 2 Coronary Stent System of the smallest/shortest (2.25/8mm), largest/shortest (5.0/12mm) and the longest lengths of every diameter balloon/stent size were tested to burst. Other sizes were also tested and required to meet rated burst requirements. All stent systems met Rated Burst Pressure. In addition, the stent/balloon burst results show statistically that with 95% confidence, 99.9% of the Express 2 MR and OTW Coronary Stent Systems will not experience balloon, shaft, or proximal/distal seal loss of integrity at or below the maximum recommended rated balloon burst pressure (18atm/265 psi for 2.25-4.0mm; 16atm/235 psi for 4.5-5.0mm).

b) Stent Nominal Sizing, Distension and Compliance Labeling

Testing was conducted to verify that the distension characteristics of the Express 2 MR and OTW Coronary Stent System meet the labeled specifications. Express, Express 2 Monorail, and Express 2 OTW utilize the identical balloon component,

stent, and crimping process, so the Express compliance data is applicable to the Express 2 MR and OTW. The stent I.D. (balloon O.D.) labeling for the Express 2 MR and OTW was leveraged from the Express Coronary Stent System testing. A minimum of thirty (30) complete Express 2 systems of each diameter and varying lengths (see table for models tested) were tested to verify the typical post deployment stent ID compliance data. In addition, a minimum of 15 units of shortest and longest sizes for each diameter were tested to verify average diameters at nominal (9 atm). The stent sizing results verify that the Express 2 MR and OTW Coronary Stent Systems meet the labeled compliance values.

c) Stent Deployment Testing

Testing was performed on the Express 2 MR and OTW Coronary Stent System to determine the stent deployment pressure and the ability of the balloon to be withdrawn from the stent. A minimum of 30 samples of each diameter (15 each of the shortest and longest of each diameter) were tested. All Express 2 MR and OTW Coronary Stent Systems met the labeled deployment specification of $\leq$ 132 psi (9 atm).

d) Balloon Inflation and Deflation Testing

Fifteen (15) each of the following Express 2 Coronary Stent Systems were tested for deflation: 4.0/16 mm OTW, 4.0/32 mm OTW, 5.0/32 mm OTW, 3.0/32 mm MR, 4.0/16 mm MR, 4.0/32 mm MR, 5.0/32 mm MR. Inflation times ranged from 1.5 – 5.0 seconds, while deflation times ranged from 6.6 – 19.0 seconds. All samples met the product specifications.

e) Repeat Balloon Inflation

Thirty samples each of the 2.25/8mm (smallest/shortest), 5.0/12mm (largest/shortest), 2.25/24mm (smallest/longest) and the 5.0/32mm (largest/longest) Express 2 delivery systems were required to complete 20 pressurization cycles to Rated Burst Pressure without failure. The stent/balloon burst results show statistically that, with 95% confidence, 90% of the catheters will not experience balloon, shaft, or proximal/distal seal loss of integrity at or below the maximum recommended rated balloon burst pressure.

f) Stent/Balloon Crossing Profile

A minimum of fifteen (15) Express 2 Coronary Stent Systems for the longest stent length of every diameter were tested to determine the deflated stent/balloon profile. Average deflated profiles of the delivery systems ranged from 0.38 – 0.55 inches. All samples met the product specification.

g) Shaft Diameters

Ten (10) 2.25/8mm and fifteen (15) 4.0/32mm Express 2 MR systems and fifteen (15) each of the 2.25/8mm and 4.0/32mm Express 2 OTW systems were tested to determine the proximal shaft, distal shaft and distal tip diameters. The Express 2

MR and OTW Coronary Stent Systems proximal shaft, distal shaft, and distal tip diameters were comparable to currently marketed stent delivery systems.

h) Pre- and Post-Deployment Catheter Withdrawal Into a Guide & Deflatibility Testing

Testing was conducted to verify that the Express 2 MR and OTW Coronary Stent Systems can be safely withdrawn back into the recommended guide catheter sizes both before and after stent deployment and the ability of the balloon to be withdrawn from the stent. Fifteen (15) each of the 4.0/32mm Express 2 Monorail and 5.0/32mm Express 2 OTW devices were tested. Pre-deployment forces ranged from 0.05 – 0.25 lbs and post-deployment forces ranged from 0.20 – 1.09 lbs indicating that Express 2 MR and OTW Coronary Stent Systems can be easily withdrawn back into the recommended guide catheter prior to and after stent deployment. All samples met the product specification.

i) Stent Securement Force Testing

Testing was conducted to assess the force required to displace a crimped stent from its catheter. A minimum of 15 test samples were used for each size tested. The shortest unit lengths (8mm for 2.25-3.5mm diameter and 12mm for 4.0-5.0 mm diameter) are considered worst case for securement because they have the least stent to balloon surface interaction. Units were tested that bracket 2.25-3.5mm and 4.0-5.0mm diameter models for both MR and OTW delivery systems. All stent systems met the stent securement specification of $\geq$ 0.2lbf. Stent securement to the specification was demonstrated with 95% confidence that 99.7% of the Express 2 MR and OTW Coronary Stent Systems will not be dislodged from the balloon.

j) System Device Tracking

Testing was conducted to demonstrate that the average work to track the Express 2 MR and OTW Coronary Stent Systems through a simulated artery is comparable to currently marketed devices. Ten (10) 3.0/16mm units of the following systems were tested: Express 2 MR, Express (Express is currently marketed outside of the United States), Express 2 OTW, and NIR™ Elite OTW (P980001/S24). The Express 2 MR ranged from 0.407-0.768 inch-lbs. while the Express ranged from 0.551-0.865 inch-lbs. The Express 2 OTW ranged from 0.283-0.363inch-lbs. while the NIR™ Elite OTW ranged from 0.398-.0513 inch-lbs. Testing demonstrated that the Express 2 MR and OTW average work through a simulated artery was comparable to currently marketed stent delivery systems. All samples met the product specification.

k) Full Unit Tensile Test

Fifteen (15) each of the 2.25/8mm, and 4.0/32mm Express 2 Monorail and 2.25/8mm Express 2 OTW Coronary Stent Systems were tested to determine the tensile strength of the Express 2 delivery catheters. The average tensile strength at

failure was 2.30, 2.24, and 3.61 lbs. respectively. All Express 2 Coronary Stent Systems exceeded the minimum catheter tensile strength specification of 1.40 lbs.

l) Packaging

Testing was conducted to determine the break free force required to dislodge an Express 2 MR or OTW manifold from its protective hoop and to determine the force required to remove the Express 2 OTW stent delivery system from its protective hoop. All Express 2 MR and OTW Coronary Stent Systems met the acceptance criteria for the break free force required to dislodge Express 2 MR and OTW manifolds from their protective hoops. Additionally the Express 2 OTW met the acceptance criteria for the force required to remove the stent delivery system from its protective hoop.

C. Animal Testing

The following *in-vitro* tests were performed in accordance with the FDA Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices, May 1994.

1. Express Feasibility Test Study

This study was performed in 4 animals to evaluate the feasibility (device design and performance) of the Express Coronary Stent System in a non-diseased swine coronary artery model. A total of 18 Express stents were implanted in a total of four (4) swine. Study endpoints were 0 hours (acute), 72 hours and 28 days (chronic). The results showed that implantation of the Express Stent in a non-diseased swine model at 72 hours and 28 days post procedure did not cause excessive thrombus, medial or adventitial damage, inflammation, or clinically significant neointimal formation.

2. Express Animal Study (GLP-204)

This study was designed to evaluate the angiographic, hemodynamic, and histological response to the BSC/Scimed Express Stent (the test device). Device performance at implant was also evaluated. Data collected includes pre and post stent Quantitative Coronary Angiography (QCA), performance ratings, vessel appearance pre stenting, post stenting and sacrifice, and histologic tissue response. Post-procedural observations were made at 72 hours and 28 days. The currently marketed NIR™ PRIMO™ was used as a control device and was implanted for 72 hours and 28 days. Implantation of the Boston Scientific/Scimed Express stent in a nondiseased swine model and sacrifice at 72 hours and 28 days did not cause excessive thrombus, inflammation or clinically significant neointimal formation. The data collected from implantation of the Express stent were within usual and expected responses for this animal model. Additionally, the Express was comparable to the control group (currently marketed products) for all performance attributes tested.

3. Performance Evaluation Express Stent on the Express 2 Delivery System in the Coronary Arteries of Swine

This study was performed to evaluate the deliverability and deployment characteristics (acute) of the Express 2 delivery system in both monorail and over-the-wire platforms. The data for the Express 2 indicated that the device was both more flexible and trackable when compared to the control group (currently marketed products). In addition, the Express 2 was comparable to the control group for all other performance attributes tested.

IX. POTENTIAL ADVERSE EFFECTS

A. Potential Adverse Events

Adverse events (in alphabetical order) which may be associated with the use of a coronary stent in native coronary arteries:

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Emboli, distal (air, tissue or thrombotic emboli)
- Emergent Coronary Artery Bypass Surgery
- Hemorrhage, requiring transfusion
- Hypotension/Hypertension
- Infection and/or pain at the access site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

B. Observed Adverse Events

A total of 450 patients were enrolled in the VICTORY Clinical Study, a prospective, multi-center, two arm registry. 303 patients were enrolled in the elective arm of the study and 147 were enrolled in the abrupt closure/threatened abrupt closure (AC/TAC) arm.

The evaluation of the Express included a comparison to a historical control comprised of randomized patients in the SCORES study who received a Radius® stent or a Palmaz-Schatz®

stent. The table below shows the major clinical events in the elective arm and the AC/TAC arm of the VICTORY Clinical Trial compared to those in the SCORES Trial.

Major Clinical Events – In-Hospital vs. Out-of-Hospital
Intent-to-Treat, All Elective Patients (N=891 pts), AC/TAC Patients (N=147)

Event	VICTORY (N=303 pts) [95% C.I.]	SCORES (N=588 pts) [95% C.I.]	AC/TAC (N=147 pts) [95% C.I.]
MACE (Death, MI TVR)	9.1% (26/287) [6.0%, 13.0%]	12.4% (71/571) [9.8%, 15.4%]	2.7% (4/146) [0.8%, 6.9%]
Early (In-hospital)	2.0% (6/303) [0.7%, 4.3%]	2.0% (12/588) [1.1%, 3.5%]	2.7% (4/147) [0.7%, 6.8%]
Out-of-hospital	7.3% (21/287) [4.6%, 11.0%]	10.5% (60/569) [8.1%, 13.4%]	0.0% (0/146) [0.0%, 2.5%]
Death - Total	0.0% (0/287) [0.0%, 1.3%]	0.4% (2/571) [0.0%, 1.3%]	0.0% (0/146) [0.0%, 2.5%]
Early (In-hospital)	0.0% (0/303) [0.0%, 1.2%]	0.3% (2/588) [0.0%, 1.2%]	0.0% (0/147) [0.0%, 2.5%]
Out-of-hospital	0.0% (0/287) [0.0%, 1.3%]	0.0% (0/569) [0.0%, 0.6%]	0.0% (0/146) [0.0%, 2.5%]
Q-wave MI - Total	0.7% (2/287) [0.1%, 2.5%]	0.5% (3/571) [0.1%, 1.5%]	0.0% (0/146) [0.0%, 2.5%]
Early (In-hospital)	0.0% (0/303) [0.0%, 1.2%]	0.0% (0/588) [0.0%, 0.6%]	0.0% (0/147) [0.0%, 2.5%]
Out-of-hospital	0.7% (2/287) [0.1%, 2.5%]	0.5% (3/569) [0.1%, 1.5%]	0.0% (0/146) [0.0%, 2.5%]
Non Q-wave MI - Total	2.8% (8/287) [1.2%, 5.4%]	1.9% (11/571) [1.0%, 3.4%]	2.7% (4/146) [0.8%, 6.9%]
Early (In-hospital)	1.7% (5/303) [0.5%, 3.8%]	1.2% (7/588) [0.5%, 2.4%]	2.7% (4/147) [0.8%, 6.8%]
Out-of-hospital	1.0% (3/287) [0.2%, 3.0%]	0.7% (4/569) [0.2%, 1.8%]	0.0% (0/146) [0.0%, 2.5%]
TVR - Total	7.7% (22/287) [4.9%, 11.4%]	10.7% (61/571) [8.3%, 13.5%]	0.0% (0/146) [0.0%, 2.5%]
Early (In-hospital)	0.3% (1/303) [0.0%, 1.8%]	0.7% (4/588) [0.2%, 1.7%]	0.0% (0/147) [0.0%, 2.5%]
Out-of-hospital	7.3% (21/287) [4.6%, 11.0%]	10.0% (57/569) [7.7%, 12.8%]	0.0% (0/146) [0.0%, 2.5%]
Stent Thrombosis - Total	1.0%(3/287) [0.2%,3.0%]	0.4% (2/571) [0.0%, 1.3%]	0.0% (0/146) [0.0%, 2.5%]
Early (In-hospital)	0.0%(0/303) [0.0%,1.2%]	0.3%(2/588) [0.0%,1.2%]	0.0% (0/147) [0.0%, 2.5%]
Out-of-hospital	1.0%(3/287) [0.2%,3.0%]	0.0%(0/569) [0.0%,0.6%]	0.0% (0/146) [0.0%, 2.5%]
Bleeding Complication	8.7% (25/288) [5.7%, 12.5%]	9.1% (52/571) 6.9%, 11.8%]	4.8% (7/146) [1.9%, 9.6%]
Early (In-hospital)	4.6% (14/303) [2.5%, 7.6%]	7.7% (45/588) [5.6%, 10.1%]	3.4% (5/147) [1.1%, 7.8%]
Out-of-hospital	4.2% (12/287) [2.2%, 7.2%]	2.1% (12/569) [1.1%, 3.7%]	1.4% (2/146) [0.2%, 4.9%]
Vascular Complication	1.0% (3/287) [0.2%, 3.0%]	0.5% (3/571) [0.1%, 1.5%]	1.4% (2/146) [0.2%, 4.9%]
Early (In-hospital)	0.0% (0/303) [0.0%, 1.2%]	0.2% (1/588) 0.0%, 0.9%]	1.4% (2/147) [0.2%, 4.8%]
Out-of-hospital	1.0% (3/287) [0.2%, 3.0%]	0.4% (2/569) [0.0%, 1.3%]	0.0% (0/146) [0.0%, 2.5%]

VICTORY Elective Stenting Study

The VICTORY Elective Registry Clinical Study was a prospective, single-arm, multi-center evaluation of the Express compared to the historical control comprised of randomized patients in the SCORES study who received a Radius® stent or a Palmaz-Schatz® stent. The VICTORY Elective Clinical Trial was conducted in the U.S. at twenty-four (24) sites out of the 26 sites with IRB approval.

The purpose of the study was to assess safety and efficacy of the Express stent in elective stenting of *de novo* and restenotic native coronary arteries (vessel diameters 3.0 – 4.0 mm and lesion lengths < 18 mm) compared with historical control. The primary endpoint was 6-month MACE. This report is an analysis of 6-month outcomes for 303 VICTORY patients and 588 SCORES patients.

The VICTORY Elective registry enrolled 303 patients: 67% male, mean age 62.1 ± 11.3 years; as compared to the SCORES cohort, which enrolled 588 patients: 71% male, mean age 60.5 ± 11.0 years. The groups were also similar with respect to prior PTCA, prior CABG, congestive heart failure, smoking status, and family history of coronary artery disease. The VICTORY cohort had higher rates of non-insulin dependent diabetes, hyperlipidemia requiring treatment, and hypertension required treatment and lower rates for history of previous MI and CCS Class IV angina.

Baseline and follow-up clinical data were collected on standardized case report forms. Protocol-mandated clinical follow-up occurred at 14 ± 4 days, 30 ± 7 days, and 6 ± 1 months (180 ± 30 days) for VICTORY patients. Six-month clinical follow-up is reported for 287/303 (95%) VICTORY patients and 571/588 (97%) SCORES patients. Follow-up Quantitative Coronary Angiography (QCA) data was available on 113/303 (37%) VICTORY patients and 148/588 (25%) SCORES patients. QCA was performed pre-procedure, following device deployment, and at 6 months post-procedure for a subset of patients. The primary endpoint for this study was 6-month MACE. The secondary endpoints included: Target Vessel Failure, Clinical Procedural Success, Technical Success, and 30-day MACE for all patients; and Angiographic Restenosis at 6 months for patients in the angiographic subset. An independent Clinical Events Committee adjudicated all MACE at regular intervals. All endpoints and covariates were analyzed on an intent-to-treat basis and on a per-protocol (received study stent per protocol) basis. Primary and secondary endpoint analyses were presented adjusted by propensity score subclass as well as unadjusted. Results for primary and secondary endpoints are shown in Exhibit 1 and Exhibit 2.

The Elective arm of the VICTORY study demonstrates that the Express™ Coronary Stent System (VICTORY) is equivalent to the historical control (SCORES) for the primary endpoint. Additionally, the acute and 6-month angiographic and clinical results showed no significant

differences between the two treatment groups with respect to the predefined secondary endpoints.

The primary endpoint was 6-month MACE. The VICTORY cohort demonstrated statistically significant non-inferiority to the SCORES cohort (upper 95% confidence limit of difference is less than 7%) using both propensity-adjusted and unadjusted rates. The intent-to-treat propensity-adjusted 6-month MACE rates for VICTORY and SCORES were 8.9% and 12.4%, respectively, giving a one-sided upper 95% confidence bound for the VICTORY−SCORES difference of 0.4%, showing non-inferiority. The Intent-to-Treat unadjusted 6-month MACE rates for VICTORY and SCORES were 9% (26/287) and 12% (71/571) respectively, giving an upper 1-sided 95% confidence bound for the difference of 0.2%, which also shows non-inferiority. The results were consistent in both intent-to-treat and per-protocol analysis sets.

Exhibit 1. Propensity Adjusted Principal Effectiveness and Safety Results Intent-to-Treat, All Elective Patients (N=891 pts)

Efficacy Measures	VICTORY (N=303 pts)	SCORES (N=588 pts)	Difference [95% CI]
Clinical Procedural Success	96.9%	96.6%	0.3% [-2.3%, 2.8%]
Technical Success	96.8%	95.5%	1.3% [-1.5%, 4.0%]
30-Day MACE	2.2%	2.2%	0.1% [-2.1%, 2.2%]
6-Month MACE	8.9%	12.4%	-3.5% [-8.1%, 1.1%]
6-Month TVF	8.9%	12.4%	-3.5% [-8.1%, 1.1%]
6-Month Restenosis	21.0%	23.8%	-2.8% [-9.3%, 3.7%]
Safety Measures			
In-Hospital MACE	1.7%	1.8%	-0.1% [-2.1%, 1.8%]
Out-of-Hospital MACE	7.3%	10.7%	-3.4% [-7.6%, 0.8%]

Exhibit 2. Unadjusted Principal Effectiveness and Safety Results Intent-to-Treat, All Elective Patients (N=891 pts)

Efficacy Measures	VICTORY (N=303 pts)	SCORES (N=588 pts)	Relative Risk [95% CI]	Difference [95% CI]
Clinical Procedural Success	97% (293/303)	96% (566/588)	1.00 [0.98, 1.03]	0.4% [-2.1%, 3.0%]
Technical Success	97% (294/303)	95% (560/588)	1.02 [0.99, 1.05]	1.8% [-0.8%, 4.4%]
30-Day MACE	2% (7/297)	2% (14/574)	0.97 [0.39, 2.37]	-0.1% [-2.2%, 2.1%]
6-Month MACE	9% (26/287)	12% (71/571)	0.73 [0.48, 1.12]	-3.4% [-7.7%, 0.9%]
6-Month TVF	9% (26/287)	12% (71/571)	0.73 [0.48, 1.12]	-3.4% [-7.7%, 0.9%]
6-Month Restenosis	19% (22/113)	24% (35/148)	0.82 [0.51, 1.32]	-4.2% [-14.2%, 5.8%]
Safety Measures				
In-Hospital MACE	2% (6/303)	2% (12/588)	0.97 [0.37, 2.56]	-0.1% [-2.0%, 1.9%]
Out-of-Hospital MACE	7% (21/287)	11% (60/569)	0.69 [0.43, 1.12]	-3.2% [-7.2%, 0.7%]

Numbers are % (count/sample size). CI = Confidence Interval.

Relative Risk = VICTORY/SCORES $\quad SE = \mathrm{sqrt}\{(1-p_1)/n_{11}+(1-p_2)/n_{21}\} \quad CI = RR \cdot \exp(\pm 1.96 \cdot SE)$

Difference = VICTORY–SCORES SE = sqrt($p_1q_1/n_1+p_2q_2/n_2$) CI = Diff±1.96·SE

Clinical Procedural Success: using the stent to achieve a residual diameter stenosis of <30% as visually assessed by the Investigator at the end of the stent procedure, without the occurrence of MACE as of the time of hospital discharge. In SCORES, the residual %DS is assessed by QCA.

Technical Success: successful delivery and deployment of the stent to the target lesion, without balloon rupture, embolization, guidewire fracture, or use of a device outside the treatment strategy. In SCORES, this is successful delivery and deployment of the stent to the target lesion without bailout.

6-Month MACE (primary endpoint): the proportion of patients who experience a MACE up to the 6-month follow-up. MACE includes death, myocardial infarction (MI) including Q- and non-Q-wave MI, and target vessel revascularization (TVR).

30-Day MACE: binary MACE rate at 30 days post-procedure.

Target Vessel Failure (TVF): any revascularization of the target vessel, or MI (Q- and non-Q-wave), or death that cannot be clearly attributed to a vessel other than the target vessel.

6-Month Restenosis: proportion of patients who demonstrate restenosis of the target lesion with percent diameter stenosis ≥50% as assessed by QCA 6 months after the study procedure.

6-Month Follow-up: 150 - 210 days.

Propensity adjusted rates are calculated to account for differences between the VICTORY and SCORES cohorts with respect to baseline variables. See the Propensity Score Analysis section for a more detailed explanation.

VICTORY AC/TAC Registry

The AC/TAC Registry arm of the VICTORY Clinical Trial was a prospective, single-arm, multi-center evaluation of the Express compared to an Objective Performance Criterion. The VICTORY AC/TAC arm of the clinical trial was conducted at nineteen (19) sites out of the 26 sites with IRB approval.

The purpose of the study was to assess safety and efficacy of the Express Stent Delivery System in AC/TAC patients compared with an Objective Performance Criterion. The primary endpoint was 14-day MACE. This report is an analysis of 14-day outcomes for 146 VICTORY patients and 30-day outcomes for 136 VICTORY Patients.

The VICTORY AC/TAC registry enrolled 147 patients: 68% males, mean age 63.0 ± 10.9 years. Other characteristics of the cohort included 29% with prior MI, 48% with Class III or IV angina, 72% with a history of hyperlipidemia requiring treatment, 70% with hypertension requiring treatment, and 31% current smokers.

Baseline and follow-up clinical data were collected on standardized case report forms. Protocol-mandated clinical follow-up occurred at 14 ± 4 days and 30 ± 7 days. Fourteen (14) day clinical follow-up is reported for 146/147 (99%) of the patients. Post-Procedure Quantitative Coronary Angiography (QCA) data was available on 145/147 (99%) VICTORY patients. QCA was performed pre-procedure and following device deployment. The primary endpoint for this study was 14-day MACE. The secondary endpoints included 30-day Target Vessel Failure, Clinical Procedural Success, Technical Success, and 30-day MACE for all patients. An independent Clinical Events Committee adjudicated all of the MACE at regular intervals. To control for inter-observer variability, an Angiographic Core Laboratory analyzed

the angiographic results for pre-procedure and post-procedure. All endpoints and covariates were analyzed on an intent-to-treat basis and on a per-protocol basis.

The AC/TAC arm of the VICTORY study demonstrates the Express™ Coronary Stent System (VICTORY) is superior to the Objective Performance Criterion of 15% with respect to the primary endpoint of 14-day MACE. The 14-Day MACE rate is 2.7% (4/146) with a 2-sided 95% C.I. of [0.8%, 6.9%] for the AC/TAC patients. The p-value from the one-sided comparison to 15% is < 0.0001; therefore, the null hypothesis of inferiority is rejected in favor of the alternative hypothesis of superiority.

Exhibit 3. Principal Effectiveness and Safety Results Intent-to-Treat, All AC/TAC Patients

Efficacy Measures	(N=147 pts)	[95% C.I.]
14-Day MACE	3% (4/146)	[0.8%, 6.9%]
30-Day TVF	3% (4/136)	[0.8%, 7.4%]
Clinical Procedural Success	96% (141/147)	[91.3%, 98.5%]
Technical Success	95% (140/147)	[90.4%, 98.1%]
30-Day MACE	3% (4/136)	[0.8%, 7.4%]
14-Day TLR	0% (0/146)	[0.0%, 2.5%]
14-Day TVR	0% (0/146)	[0.0%, 2.5%]
Safety Measures and Other Clinical Events		
In-Hospital MACE	3% (4/147)	[0.7%, 6.8%]
Out-of-Hospital 14-Day MACE	0% (0/146)	[0.0%, 2.5%]

Numbers are % (count/sample size). C.I. = Confidence Interval.

Exact binomial confidence limits are given for proportions.

The primary endpoint is the proportion of patients who experience a MACE within 14 days after the procedure. MACE includes death, myocardial infarction (MI) including Q- and non-Q-wave MI, and target vessel revascularization (TVR).

Target Vessel Failure (TVF): any revascularization of the target vessel, or MI (Q- and non-Q-wave), or death that cannot be clearly attributed to a vessel other than the target vessel. Assessed at 1 month for AC/TAC patients.

Clinical Procedural Success: using the stent to achieve a residual diameter stenosis of <30% as visually assessed by the Investigator at the end of the stent procedure, without the occurrence of MACE as of the time of hospital discharge.

Technical Success: successful delivery and deployment of the stent to the target lesion, without balloon rupture, embolization, guidewire fracture, or use of a device outside the treatment strategy.

Target Lesion Revascularization (TLR): Revascularization of the target lesion.

Target Vessel Revascularization (TVR): Revascularization of the target vessel, including or not including the target lesion.

14-Day MACE is the number of patients who had a MACE within 18 days of the procedure out of the number of patients who had a follow-up at least 10 days after the procedure.

30-Day TVF (MACE) is the number of patients who had a TVF (MACE) within 37 days of the procedure out of the number of patients who had a follow-up at least 23 days after the procedure.

Gender Bias

The VICTORY clinical trial was designed and conducted to avoid gender bias in patient enrollment. Of the 450 patients enrolled, 304 (67.6%) were male. The ratio of males to females in this study is consistent with other trials of coronary stents.

Univariate analyses were conducted which evaluated the effect of gender on the following clinical and angiographic outcomes at 6 months: TVR, MACE, binary angiographic restenosis, follow-up percent diameter stenosis, and follow-up in-lesion MLD. Gender was not significantly associated with any of the clinical outcomes and was only associated with the angiographic outcome of MLD at 6 months. Females had slightly smaller mean MLDs (1.75 mm vs. 1.98 mm) at 6 months. This result is as expected since females tend to have smaller coronary arteries. Since clinical outcomes were not associated with gender, these data demonstrated that gender was not an influencing factor on safety or effectiveness.

XI. CONCLUSIONS FROM CLINICAL AND NON-CLINICAL STUDIES

Non-clinical studies of the Express/Express 2 MR/Express 2 OTW Coronary Stent System demonstrate that the devices are adequate for their intended use.

Clinical studies data demonstrate that the Express Coronary stent system is both safe and effective for its intended use. The Express Coronary Stent System was the device used in the VICTORY Clinical Trial. The Express 2 MR and OTW Coronary Stent Systems are modified versions of the Express Coronary Stent System, in which the Express stent has been pre-mounted on different delivery systems. Clinical data from this study (VICTORY Clinical Trail) are directly applicable to the Express 2 MR and OTW Coronary Stent Systems based on comparative *in vitro* performance of the stent system.

The Elective arm of the VICTORY study demonstrates that the Express™ Coronary Stent System (VICTORY) is equivalent to the historical control (SCORES) for the endpoint. Additionally, the acute and 6-month angiographic and clinical results showed no significant differences between the two treatment groups with respect to the predefined secondary endpoints.

The primary endpoint was 6-month MACE. The VICTORY cohort demonstrated statistically significant non-inferiority to the SCORES cohort (upper 95% confidence limit of difference is less than 7%) using both propensity-adjusted and unadjusted rates. The intent-to-treat propensity-adjusted 6-month MACE rates for VICTORY and SCORES were 8.9% and 12.4%, respectively, giving a one-sided upper 95% confidence bound for the VICTORY−SCORES difference of 0.4%, showing non-inferiority. The Intent-to-Treat unadjusted 6-month MACE rates for VICTORY and SCORES were 9% (26/287) and 12% (71/571) respectively, giving an upper 1-sided 95% confidence bound for the difference of 0.2%, which also shows non-inferiority. The results were consistent in both intent-to-treat and per-protocol analysis sets.

The AC/TAC arm of the Victory study demonstrates the Express™ Coronary Stent System (VICTORY) is superior to the Objective Performance Criterion of 15% with respect to the primary endpoint of 14-day MACE. The 14-Day MACE rate is 2.7% (4/146) with a 2-sided 95% C.I. of [0.8%, 6.9%] for the AC/TAC patients. The p-value from the one-sided comparison to 15% is < 0.0001; therefore, the null hypothesis of inferiority is rejected in favor of the alternative hypothesis of superiority.

XII. PANEL RECOMMENDATION

In accordance with the 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 Panel, and FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

CDRH issued a letter to Boston Scientific Scimed, Inc. on July 1, 2002 advising that it PMA was approvable subject to changes in the labeling and acceptable results from inspections of the manufacturing facilities. The applicant provided the required changes in the labeling and the applicant's manufacturing facilities were inspected on March 7, July 7 and 10, 2002 and were found to be in compliance with the Quality System Regulation (21 CFR 820). CDRH approved this PMA application on September 11, 2002.

XIV. APPROVAL SPECIFICATIONS

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.