SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

Device Generic Name:	Percutaneous Transluminal Coronary Angioplasty Catheter
Device Trade Name:	FX miniRAIL™ RX Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Premarket Approval (PMA) Number:	P020037
Date of Panel Recommendation:	none
Name/Address of Applicant:	X Technologies, Inc. 15042 Parkway Loop, Suite A Tustin, California 92780
Date of Notice of Approval to the Applicant :	June 11, 2003

II. INDICATIONS

The FX miniRAIL™ Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery, including in-stent restenosis, for the purpose of improving myocardial perfusion.

III. CONTRAINDICATIONS

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of significant stenosis

IV. WARNINGS AND PRECAUTIONS

A list of warnings and precautions can be found in the device labeling.

V. DEVICE DESCRIPTION

The FX miniRAIL™ is a PTCA catheter, which features a semi-compliant balloon that is designed to expand to a specified diameter and length at a specified pressure. The balloon is connected to a distal tip, which houses a short guidewire lumen. The proximal end of the balloon is connected to an inflation channel, which floats freely inside a stainless steel hypotube catheter shaft. A pull wire connects the hypotube shaft to the distal tip. Two radiopaque markers are mounted on the pull wire such that they delineate the working segment of the balloon and facilitate fluoroscopic visualization of the balloon during use. The device is available in balloon diameters of 2.0-4.0 mm and lengths of 10-30 mm.

The FX miniRAIL™ design has the following structural and functional characteristics:

- Pushing force is transmitted from the catheter shaft through the pull wire to the distal tip.
- The dilatation balloon and inflation channel are separated from the catheter shaft to minimize the catheter crossing profile.
- The guidewire lumen is 12 mm in length. This facilitates single operator catheter exchange.

The balloon is designed to be inflated both against the stationary guidewire and the pull wire to concentrate the dilatation force exerted on the lesion.

VI. ALTERNATIVE PRACTICES/PROCEDURES

Alternative treatments for coronary artery disease include medical therapy, coronary atherectomy, coronary laser, coronary stent, coronary endarterectomy, coronary artery bypass graft surgery, and other commercially available PTCA catheters.

VII. MARKETING HISTORY

The FX miniRAIL™ received a CE mark in Europe in December 2001, with addition of the in-stent restenosis indication in January 2002 and addition of the 10 mm balloon size in May 2002. The device is available for commercial sale in the following countries: Austria, Belgium. Germany, Greece, Hong Kong, Israel, Italy, Malaysia, the Netherlands, Singapore, Spain, Switzerland, Turkey, and the United Kingdom. The device has not been withdrawn from any country for reasons relating to device safety and effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF DEVICE ON HEALTH

Possible adverse effects associated with percutaneous transluminal coronary angioplasty include, but are not limited to:

- Coronary vessel dissection, perforation, rupture, or other injury
- Arrhythmias, including ventricular fibrillation, or other conduction disturbances
- Acute myocardial infarction ("MI")
- Unstable angina
- Arteriovenous fistula
- Coronary artery spasm
- Total occlusion of the coronary artery
- Hemorrhage or hematoma
- Thrombosis
- Embolism
- Infection
- Allergic reaction to medications or contrast media
- Hypo/hypertension
- Death

A summary of the adverse events observed in the multi-center IDE study is provided in tabular form below.

Summary of Principal Adverse Event Rates Observed in the IDE Study*

Event	Number of Events	% of Patients (N)
Major Adverse Coronary Events (MACE)		
Total MACE	7	2.8% (7/248)
Death	0	0% (0/248)
Q wave MI	2	0.8% (2/248)
Non-Q wave MI**	4	1.6% (4/248)
Target Lesion Revascularization (TLR)	3	1.2% (3/248)
CABG	1	0.4% (1/248)
PTCA	2	0.8% (2/248)
Non-MACE Major Cardiovascular Events		
Total occlusions	2	0.8% (2/248)
Acute stent thrombosis (to 24 hours)	1	0.4% (1/263)
Sub-acute stent thrombosis	1	0.4% (1/263)
Perforations***	2	0.8% (2/263)
Bleeding/Vascular complications****	9	2.0% (5/263)
Vascular events requiring transfusion	5	1.2% (3/263)

*Except for acute stent thrombosis and bleeding, which are evaluated in hospital, and perforations, which are evaluated during the procedure, the adverse event rates reported above are based on the 248 of 263 patients for whom post-discharge follow-up was available through at least seven days post-procedure.
**Non-Q wave MI is defined as the absence of new pathologic Q waves on ECG and a total CK of greater than 3 times normal (as defined by the hospital laboratory) with an elevated MB fraction. If total CK was unavailable, an MB fraction of greater than 3 times the normal level was used. Both perforations were iatrogenic, one caused by the guidewire and the other due to an error in catheter introduction.
*** Includes hematoma, retroperitoneal bleed, GI bleed, anemia, and oral bleeding.

In addition to MACE (*i.e.*, death, MI, or TLR), a total of 51 non-MACE cardiovascular events were observed in 38 patients, along with 28 non-cardiovascular events in 24 patients. Among the non-MACE, the principal cardiovascular events were ischemia, arrhythmia, hyper/hypotension, and bleeding/vascular complications. The principal non-cardiovascular event was pain, primarily back and/or head and neck pain. No other events occurred in more than 1 % of patients.

None of these events were unanticipated, and the nature and frequency of events were similar to other PTCA catheters. None of these events was serious, and the events generally resolved without intervention other than routine medications (*e.g.*, pain relievers), except for several cases of bleeding at the insertion site that required transfusion, and one case of hypotension which required pharmacological treatment.

IX. SUMMARY OF PRECLINICAL STUDIES

Nonclinical testing of the FX miniRAIL™ was performed in accordance with FDA's Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices and relevant industry standards. The results of these tests are briefly summarized below.

A. In Vitro Performance Testing

Balloon Rated Burst Pressure

A total of 519 catheters were tested to establish the rated burst pressure, including devices of all balloon diameter sizes. Burst testing was conducted both with an unconstrained balloon (N = 428) and with the balloon inflated to burst in a simulated vessel (N = 91). A table summarizing the mean burst pressure, rated burst pressure, and recommended pressure in atmospheres for each balloon size is included below. The burst pressure data were analyzed to determine with 95% confidence that 99.9% of balloons would not burst at or below the calculated rated burst pressure. All balloon catheters had rated burst pressures ("RBP") > 13.0 atm. The specified RBPs in **Table 1** provide an ample margin of safety relative to the nominal inflation pressure of 8 atm.

Table 1. Rated Burst Pressure (atm)

SIZE	Mean Unconstrained/ Constrained	Calculated RBP	Recommended RBP
2.0 mm	24.4/26.1	16.7	14
2.5 mm	20.7/23.3	14.2	13
3.0 mm	21.6/24.6	13.6	13
3.5 mm	22.4/24.4	18.6	13
4.0 mm	20.2/23.6	13.0	12

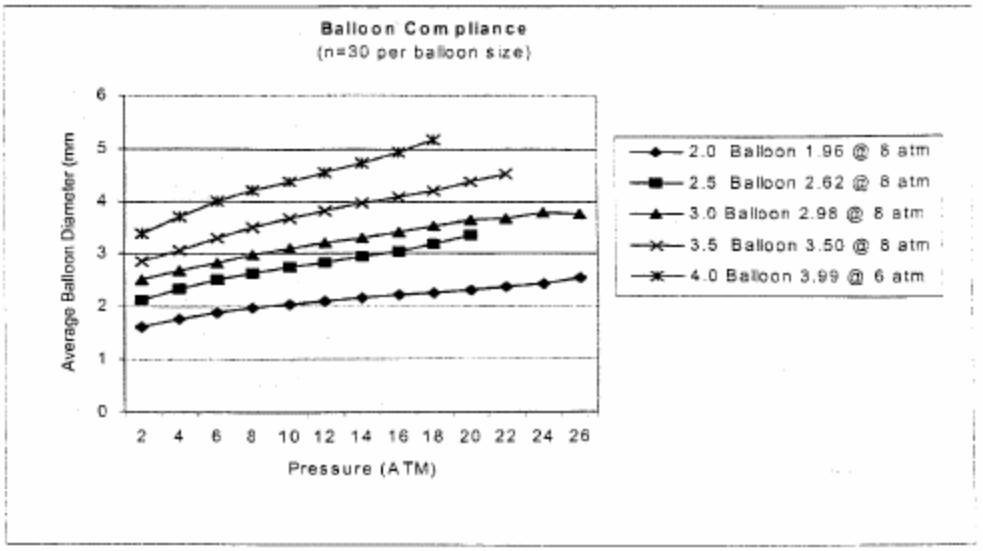
Balloon Fatigue Testing

Balloon fatigue testing included at least ten catheters from each of the following sizes: smallest diameter/shortest length, smallest diameter/longest length, largest diameter/shortest length, largest diameter/longest length, and ten catheters from each of the other diameters for a total of 90 test samples. A total of 101 samples were actually tested due to additional fatigue testing of shelf life samples. Thirty-eight of the 101 catheters were subjected to a total of 40 fatigue cycles, while the remainder were subjected to the required 20 cycles. The test cycle consisted of inflation to a pressure of 14 atm with the pressure held at 14 atm for 30 seconds, followed by deflation to a vacuum state. A .014" guidewire was inserted through the catheter tip and across the balloon prior to being positioned in a simulated artery. The catheters were continuously monitored for leakage and inspected every ten cycles for any visual anomalies. The results met the acceptance criteria for the test, i.e., 90% or greater pass at the 95% confidence interval.

Balloon Distensibility

The objective of this test was to evaluate the change in balloon diameter versus inflation pressure. These tests were conducted on 418 functional, complete, or shortened

(to facilitate testing) catheters. The sizes tested were 30 mm length, all diameters, plus 10 and 15 mm lengths for the 2.0 mm and 4.0 mm diameters, to establish the compliance



profile. The figure above shows balloon compliance for each balloon size and indicates the pressure at which the labeled (nominal) balloon diameter is attained. These data are also included in the device labeling.

Catheter Preparation/Inflation and Deflation

Catheter preparation testing was performed on 121 devices in an environment that simulates use in a coronary artery. Catheters were subjected to the following test sequence: (1) visual and dimensional inspection, (2) a preparation and leakage test, and (3) an inflation/ deflation balloon fatigue test. The results of these tests are provided in **Tables 2, 3 and 4** below.

Table 2. Balloon Preparation and Leakage

Balloon Size	Sample Size	Leakage after 5 sec?	Purge within 5 sec?
2.0 mm x 15 mm	30	No (Pass)	Yes (Pass)
2.0 mm x 30 mm	30	No (Pass)	Yes (Pass)
4.0 mm x 15 mm	30	No (Pass)	Yes (Pass)
4.0 mm x 30 mm	31	No (Pass)	Yes (Pass)

Table 3. Balloon Inflation/Deflation Performance (3 Cycles)

Balloon Size	Sample Size	Inflation in < 10 sec?	Deflation in < 20 sec?
2.0 mm x 15 mm	30	Yes (Pass)	Yes (Pass)
2.0 mm x 30 mm	30	Yes (Pass)	Yes (Pass)
4.0 mm x 15 mm	30	Yes (Pass)	Yes (Pass)
4.0 mm x 30 mm	31	Yes (Pass)	Yes (Pass)

Table 4. Visual and Dimensional Inspection

Visual Inspection	Proximal Shaft Diameter 2.8F	Distal Shaft Diameter 3.1F	Shaft Marker Locations 90 &100cm	Catheter Length 140cm
Pass	Pass	Pass	Pass	Pass

All samples met the acceptance criteria.

Bond Strength

All bonded and welded joints in the FX miniRAIL™ were tested following preconditioning in a 37°C water bath. Fifteen samples of each bond were tested. All test data exceeded the specification limit for bonded joints. For the welded joint, the test data exceeded the load cell capacity of 50 N pull force. Base material broke on all samples.

Over-the-Arch Torque Response and Torque Strength

The objective of these tests was to determine the torque response and strength of the catheter under two conditions: (1) when its distal tip was free to rotate, and (2) when its distal tip was fixed. The catheter was inserted into a test fixture, which consists of a simulated aortic arch and coronary artery. Fifteen catheters were included in each test. In the first test condition, the proximal end was rotated with the distal tip unconstrained until failure occurred. The number of rotations to failure and the mode of failure for each sample tested were recorded. All test units were able to maintain functionality after two complete rotations.

In the second test condition, a torque strength test was performed to determine the ability of the FX miniRAIL™ Catheter to withstand extreme torque under simulated use conditions "over-the-arch" when the tip of the catheter is not free to rotate and either the shaft or the inflation luer fitting is rotated (which is not likely to happen in the clinical setting). Fifteen catheters were tested. The results demonstrated that the inflation/deflation function of the FX miniRAIL™ is not impaired after five complete rotations of the inflation lumen.

Radiodetectability

Evaluation of five FX miniRAIL™ Catheters compared to two commercially available catheters demonstrated comparable radio detectability on fluoroscopy in a porcine model.

Corrosion

Corrosion resistance of the catheter was conducted in accordance with standard methods for evaluation of balloon dilatation catheters (ISO 10555-1). A total of 15 catheters were evaluated. The results demonstrated no corrosion of any of the metal parts, including the radiopaque marker bands, the hypotube, and the pull wire.

B. Biocompatibility Testing

The objective of these tests was to establish the Biocompatibility of the FX miniRAIL™ Catheter. Testing was conducted consistent with the requirements of FDA Program Memorandum #G95-1 (Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices part 1: Evaluation and Testing") and ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, for externally communicating devices that contact circulating blood for a limited duration (< 24 hours). These tests included cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, hemocompatibility (hemolysis, thrombogenicity, thromboresistance, and complement activation), and pyrogenicity. No significant adverse findings were noted.

C. Shelf Life, Packaging, and Sterilization Testing

The objective of these tests was to establish a 24-month shelf life for the FX miniRAIL™ Catheter in its final package. Following sterilization and extreme conditioning (thermal cycling), finished devices were exposed to accelerated aging, shipping simulation testing similar to the original verification, and validation testing.

Product packaging was subjected to integrity tests, which at the 24-month time frame included seal pull and bubble emission tests, while the finished catheters were subjected to functional tests including balloon compliance, burst, function, and performance. The results met all acceptance criteria.

The FX miniRAIL™ is sterilized using ethylene oxide ("EtO") according to parameters that have been validated to produce a sterility assurance level of at least 10^{-6}. Residuals are within acceptable limits.

D. Animal Testing (In Vivo)

Animal testing was conducted in two phases. Following preliminary prototype evaluation, testing of the final device configuration in a porcine model was performed. Catheter insertion was randomized to LAD and circumflex ("LCX") arteries in five pigs, with balloon inflation controlled by on-line quantitative coronary angiography (QCA) to a balloon artery ratio of 1.0 : 1.2. Histopathology examination was performed at an independent laboratory. No adverse events or clinically significant histopathology findings were noted.

Based on the examination of over 235 tissue samples and on angiography analysis, the study concluded that there was no evidence of perforation or laceration in either group and that the degree of injury resulting from passage and inflation of the FX miniRAIL™ Catheter was similar to or less than a standard PTCA catheter.

X. SUMMARY OF CLINICAL STUDIES

A multi-center, non-randomized, single-arm prospective clinical trial was conducted to evaluate the safety and effectiveness of the FX miniRAIL™ Catheter in patients with single or multiple vessel coronary artery disease who were scheduled to undergo percutaneous coronary intervention because of symptoms of stable or unstable angina pectoris. Twelve sites entered a total of 263 patients (366 lesions) eligible for elective coronary angioplasty who met the inclusion/exclusion criteria. The hypothesis of the study was that the procedural success rate and clinical success rate for the FX miniRAIL™, as defined below, were equivalent to objective performance criteria based on contemporary published literature.

Eligibility Criteria

Principal inclusion criteria for the study were as follows: (1) single or multiple vessel coronary artery disease in subjects who are scheduled to undergo percutaneous coronary intervention because of symptoms of stable or unstable angina pectoris; (2) stenotic lesions in native coronary arteries, including in-stent restenosis; (3) lesions with a reference vessel diameter ("RVD") of between 2.0 mm and 4.0 mm. Principal exclusions were as follows: left ventricular ejection fraction < 35%; contraindication to CABG, antiplatelet and/or anticoagulation medications; severe renal failure with creatinine $\geq$ 2mg/dL; pregnancy; symptoms of cardiogenic shock; acute myocardial infarction or an MI within the past three days, and/or elevated CPK at the time of enrollment; totally obstructed coronary arteries (TIMI 0 or 1 flow); lesions longer than 30 mm; visible thrombus in angiography; an "unprotected" left main coronary artery (> 50% diameter

stenosis); requiring treatment of more than three lesions or more than two vessels; coronary spasm in the absence of a significant stenosis; severe calcification by visual assessment; requiring treatment with atherectomy; and lesions in surgical conduits — saphenous vein grafts, internal mammary arteries, or radial arteries. Patients who underwent a staged procedure 30 days prior to enrollment and/or were scheduled to have a staged procedure 14 days after treatment with the FX miniRAIL™ were also excluded from participation.

Methods

The primary endpoints for the study were procedural success and clinical success. Procedural success was defined as <50% final diameter stenosis in at least one of the FX-attempted lesions without death, Q wave or non-Q wave MI, or emergency CABG during hospital stay. Clinical success was defined as freedom from MACE, defined as death, any MI (Q wave or non-Q wave), or target lesion revascularization (TLR) at 14-day follow-up. Coronary angiography, consistent with QCA standards, was performed before and immediately after angioplasty with the FX miniRAILTM Catheter. Stenosis resolution was measured by on-line QCA. The initial, post-FX, and final lesion status were assessed both by on-line and off-line QCA, measuring percentage of diameter stenosis, percentage of area stenosis, post-FX minimal luminal diameter, and mean reference diameter. Other balloon/procedure data, such as stenosis resolution pressure and inflation time, also were collected. Intravascular ultrasound ("IVUS") examination was also performed on a subset of 55 patients to evaluate the effect of the device on the vascular lumen. All major adverse clinical events were source documented and adjudicated by an independent clinical events committee (CEC).

Baseline Characteristics

Of the 263 patients treated, 12 were enrolled in the roll-in phase and 251 were enrolled in the pivotal or registry phase of the study. Results are reported below principally for the 251 patients enrolled in the registry phase, although no significant differences in procedural success or clinical success were noted between the roll-in and registry cases. Baseline demographics and clinical characteristics showed a mean age of 63.8 ± 10.5 years, with 73.3% (184/251) male participants and 32.3% (81/251) with a history of diabetes mellitus. The principal baseline characteristics of the study population are summarized in **Table 5** below.

Table 5. Summary of Patient Baseline Characteristics

Patient Characteristics	Aggregate
Age	
Mean + SD (n)	63.8+/- 10.5 (251)
Range (min, max)	(35, 88)
Gender: Male	73.3% (184/251)
Current Smoker	15.1% (38/251)
Diabetes	32.3% (81/251)
History of Hypertension	72.9% (183/251)
History of Hypercholesterolemia	72.9% (183/251)
Prior MI	40.2% (101/251)
Prior CABG	16.7% (42/251)
Prior PTCA	58.6% (147/251)
Angina	84.9% (213/251)
Stable Angina	52.2% (131/251)
Unstable Angina	32.7% (82/251)
Canadian Cardiovascular Society (CCS) Angina Class III/IV	39.0% (98/251)
Ejection Fraction: Normal (> 50%) 35-50% < 35%	 78.4% (192/245) 20.0% (49/245) 1.6% (4/245)

Pre-procedure Medication	
Aspirin	94.0% (236/251)
Plavix	51.6% (129/250)
Ticlid	0.4% (1/249)

Baseline lesion characteristics based on QCA assessment are summarized in **Table 6** below.

Table 6. Baseline Lesion Characteristics*

Patient Characteristics	Aggregate	95% Confidence Interval
Vessel Diameter** (mm)		
Mean + SD (n)	2.80 +/- 0.49 (319)	(2.74, 2.85)
Range (min, max)	(1.61, 4.57)	
Minimum Lumen Diameter **(mm)		
Mean + SD (n)	0.92 +/- 0.40 (320)	(0.87, 0.96)
Range (min, max)	(0.00, 2.10)	
Diameter Stenosis %		
Mean + SD (n)	67.36 +/- 12.81 (319)	(65.95, 68.77)
Range (min, max)	(29.32, 100.00)	
Lesion Length		
Mean + SD (n)	12.69 +/- 7.15 (317)	(11.90, 13.48)
Range (min, max)	(2.00, 60.28)	
Lesion Vessel		
RCA	29.0% (93/321)	(24.1%, 34.3%)
LAD	38.0% (122/321)	(32.7%, 43.6%)
Circumflex	31.8% (102/321)	(26.7%, 37.2%)
SVG**	1.2% (4/321)	(0.3%, 3.2%)
Calcification: Moderate/Severe	8.8% (28/320)	(5.9%, 12.4%)
Thrombus**	2.2% (7/320)	(0.9%, 4.5%)
Eccentric Lesion	28.1% (90/320)	(23.3%, 33.4%)
Angulation > 45 degrees	5.6% (18/320)	(3.4%, 8.7%)
ACC/AHA Lesion Class		
MACC Score A	11.8% (38/321)	(8.5%, 15.9%)
MACC Score B1	44.5% (143/321)	(39.0%, 50.2%)
MACC Score B2	32.4% (104/321)	(27.3%, 37.8%)
MACC Score C	0.0% (0/321)	(0.0%, 1.1%)
Total Occlusions Treated**	1.2% (4/321)	(0.3%, 3.2%)

*Baseline characteristics are reported for a total of 321 of the 349 intention-to-treat FX miniRAIL™ lesions (in 251 registry patients) for which baseline QCA was available.

**In some instances, patients who were included based on visual examination were found upon QCA to present lesions that were slightly outside the eligibility criteria, *e.g.*, due to diameter, vessel type, length, presence of thrombus, or total occlusion. However, because eligibility was determined based on visual examination, these were not regarded as protocol deviations.

Results

Data analysis was performed on an intent-to-treat basis. With respect to procedural success, all 251 registry patients were included in the analysis, except for three patients for whom QCA data were not available to permit evaluation of residual stenosis. Among this group of 248 patients, the procedural success rate was 94.8% (235/248). With respect to clinical success, which required post-discharge follow-up for evaluation of non-acute MACE (*i.e.*, death, MI, or TLR), the analysis included the 238 patients in the pivotal phase of the study for whom at least a seven-day follow-up post-procedure was available. Among this group, the clinical success rate was 97.1% (231/238).

Table 7. Summary of Primary Endpoints

Effectiveness Measures	Aggregate	95% Confidence Interval
Procedural Success (In-hospital)	94.8% (235/248)	(91.2%, 97.2%)
Clinical Success	97.1% (231/238)	(94.0%, 98.8%)

These rates met the study hypothesis, *i.e.*, of observed procedural success no less than the historical rate of 92% (OPC) ± 7% (delta), and of observed clinical success (MACE-free at the post-discharge follow-up visit) no less than the historical rate of 95% (OPC) ± 7% (delta). In both cases, the aggregate value exceeds the objective performance criterion that was established based on the historical literature, and the lower limits of the confidence intervals with respect to each endpoint are well above the minimum required to demonstrate equivalence.

Further analysis of the components of each of the primary endpoints is provided in **Table 8** below.

Table 8. Analysis of Components of Primary Endpoints

Effectiveness Measures	Aggregate	95% Confidence Interval
Procedural Success	94.8% (235/248)	(91.2%, 97.2%)
> 50% residual diameter stenosis	2.8% (7/248)	(1.1%, 5.7%)
In-hospital Death	0.0% (0/251)	(0.0%, 1.5%)
In-hospital MI (Q wave or non-Q wave)	2.0% (5/251)	(0.7%, 4.6%)
Emergent CABG	0.4% (1/251)	(0.2%, 3.5%)
Clinical Success	97.1% (231/238)	(94.0%, 98.8%)
Death (at post-discharge follow-up)	0.0% (0/238)	(0.0%, 1.6%)
MI (at post-discharge follow-up)	2.5% (6/238)	(1.0%, 5.8%)
Q wave MI	0.8% (2/238)	(0.1%, 3.2%)
Non-Q wave MI	1.7% (4/238)	(0.5%, 4.5%)
TLR	1.3% (3/238)	(0.3%, 3.6%)

Of the 13/248 patients who were not procedural successes, six failed due to in-hospital MACE, and seven failed due to residual stenosis > 50%. As illustrated in **Table 9** below, among the 238 patients who returned for follow-up at least seven days post-procedure, seven experienced MACE. Six of the patients experienced MACE while in the hospital, and one experienced MACE (a non-Q wave MI related to a subsequent non-target lesion revascularization, not to the FX miniRAIL™) outside the hospital at eight days post-procedure. MACE rates were calculated per patient; thus, while several of the patients experienced more than one MACE, each patient was counted only once. In total, there were nine events among these seven patients (four non-Q wave MI, two Q wave MI, and three TLR).

Table 9. Combined (In-Hospital and Post-Discharge) Complications*

Event	% (N)	95% C.I.
MACE (Death, MI, TLR)	2.9% (7/238)	(1.2%, 6.0%)
Death	0.0% (0/238)	(0.0%, 1.5%)
Cardiac Death	0.0% (0/238)	(0.0%, 1.5%)
Non Cardiac Death	0.0% (0/238)	(0.0%, 1.5%)
MI	2.5% (6/238)	(0.9%, 5.4%)
Q wave MI	0.8% (2/238)	(0.1%, 3.0%)
Non-Q wave MI	1.7% (4/238)	(0.5%, 4.2%)
Target Lesion Revascularization	1.3% (3/238)	(0.3%, 3.6%)
PTCA	0.8% (2/238)	(0.1%, 3.0%)
CABG	0.4% (1/238)	(0.0%, 2.3%)
Target Vessel Revascularization	1.3% (3/238)	(0.3%, 3.6%)
PTCA	0.8% (2/238)	(0.1%, 3.0%)
CABG	0.4% (1/238)	(0.0%, 2.3%)
Total Occlusions	0.8% (2/238)	(0.1%, 3.0%)

*Because assessment of out-of-hospital events required post-discharge follow-up, these variables are reported for the 238 of 251 registry patients for whom post-discharge follow-up of at least seven days was completed.

With regard to other measures of device safety, the rate and type of dissections observed upon angiography after use of the FX miniRAIL™ was consistent with other PTCA investigations. Only two perforations were observed in the investigation, neither of which was determined to be due to the FX miniRAIL™. Additional evidence of the safety of the device is available from IVUS examination of the lesions, which was performed in a subset of 55 lesions in 42 patients at two investigational sites. The results of this supplementary analysis also demonstrated that the type and rate of dissections were similar to other PTCA catheters. A total of 12 failures to cross the target lesion were observed that were deemed to be device-related, including two device malfunctions, three instances of “melon seeding, “ and seven cases in which the device was unable to cross the target lesion, but another catheter subsequently crossed the lesion. There were

also three failures to cross the lesion not related to the study device (*e.g.*, cases where no device was able to cross, or other procedural issues).

Further analysis of the data for the 77 patients with only in-stent restenosis ("ISR") lesions compared to the 160 patients with only non-ISR lesions demonstrated no significant differences in either procedural success rates or clinical success rates based on lesion type. These results are summarized in the table below.

Table 10. Comparison of Outcomes in Patients with ISR versus non-ISR Lesions*

	ISR	Non-ISR	p-value
Clinical Success	97.2%0 (70/72)	97.4% (148/152)	1.00
Procedural Success	92.1% (70/76)	96.8% (153/158)	0.18
MACE	2.8%(2/72)	2.6% (4/152)	1.00
In-Hospital MACE	2.6%(2/77)	1.9% (3/160)	0.66
Out-of-Hospital MACE	0.0%(0/72)	0.7% (1/152)	1.00
Death	0.0%(0/72)	0.0% (0/152)	N/A
MI	2.8%(2/72)	2.0% (3/152)	0.66
Q wave MI	2.8%(2/72)	0.0% (0/152)	0.10
Non-Q wave MI	0.0%(0/72)	2.0% (3/152)	0.55
TLR	1.4% (1/72)	0.7% (1/152)	0.54
Total Occlusions (at post-discharge follow-up)	1.4%(1/72)	0.0% (0/152)	0.31
Acute Stent Thrombosis (to 24 hours)	0.0% (0/77) *	0.0% (0/160)	N/A

* There were 72 ISR cases with sufficient post-procedure follow-up for evaluation of clinical success: 76 with in-hospital data up to discharge; and 77 with 24-hour in-hospital data.
** Patients with both ISR and non-ISR lesions were excluded.

Multivariate analysis also indicated that gender, diabetes, and investigational site did not significantly impact outcomes.

The additional procedural data that were collected demonstrated a mean stenosis resolution pressure of 6.14 +/- 2.51 atm, and a mean maximum inflation pressure of 8.49 +/- 2.90 atm, which is well below the rated burst pressure for the device.

In addition to the IDE study described above, a 30-patient registry study was conducted at a single center in Germany in 2001 to support CE marking of the device. The eligibility criteria and methods used in this study were generally similar to the IDE study described above. The primary endpoints also were similar, although the definitions of procedural success and clinical success differed slightly (*e.g.*, MACE collected through 30 days, defined to include Q wave MI but not non-Q wave MI). However, the results were consistent with the IDE study, with procedural and clinical success rates of 100%. Commercial experience with the FX miniRAIL™ in Europe since receipt of the CE mark further supports the safety and efficacy of the device.

XI. CONCLUSIONS DRAWN FROM STUDIES

The results of the pivotal IDE study described above demonstrate that the FX miniRAIL™ is reasonably safe and effective for use in PTCA procedures. The procedural success and clinical success rates that were observed in this investigation are equivalent to those reported in similar historical studies of other PTCA catheters that have been published in the medical literature. The rate and type of MACE also are similar to those associated with other PTCA catheters. The use of a wire external to the device and the resultant reduced crossing profile, permitted effective lesion dilatation, and did not result in any observed increase in MACE rates or perforations/dissections. The study also demonstrates that the FX miniRAIL™ can be used in either ISR or *de novo* lesions with similar safety and effectiveness. These results were confirmed by a separate single-center investigation conducted in Europe and supported by subsequent

commercial experience. Thus, the device is reasonably safe and effective for its intended use.

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 Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by the panel.

XIII. FDA DECISION

The applicant's manufacturing facilities were inspected on 4/9/02 and 12/20/02 and found to be in compliance with the Quality System Regulation (21 CFR Part 820). FDA issued a PMA approval order to X Technologies, Inc. on June 11, 2003.

XIV. APPROVED SPECIFICATIONS

Direction for use: See Device Labeling

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, and Precautions, and Adverse Events in the Final Draft Labeling, Indication for Use.

Post-approval Requirements and Restrictions: See Approval Order.