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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ENDOVASCULAR TECHNOLOGIES, INC., Defendant.	No. CR 02-0179 SI PLEA AGREEMENT

ENDOVASCULAR TECHNOLOGIES, INC., a wholly owned subsidiary of Guidant Corporation, ("defendant"), and the United States Department of Justice, by the United States Attorney's Office for the Northern District of California and the Office of Consumer Litigation ("the government") enter into this written Plea Agreement (the "Agreement") pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure:

Defendant's Promises

1. Defendant agrees to waive indictment and plead guilty to a criminal Information

charging it with one felony count of making false statements within the jurisdiction of a federal agency, in violation of 18 U.S.C. § 1001, and nine felony counts of shipping misbranded medical devices in interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). Defendant agrees that the elements of the offense of making false statements within the jurisdiction of a federal agency are as follows: (1) defendant made a false statement or representation; (2) the defendant acted knowingly and willfully, that is deliberately and with knowledge that the statement or representation was untrue; and (3) the statement or representation was material to the activities or decision of a government agency or department, meaning that the statement or representation could have influenced the agency's decisions or activities. Defendant agrees that the maximum penalties for making a false statement are as follows:

a.	Maximum fine	$500,000 or the greater of twice the gross gain or twice the gross loss
b.	Maximum term of probation	5 years
c.	Mandatory special assessment	$400
d.	Restitution	Up to the amount of the loss

Defendant agrees that the elements of the offense of shipping misbranded medical devices in interstate commerce are as follows: (1) that defendant caused a device to be introduced, and delivered for introduction, into interstate commerce; (2) the device was misbranded when it was so introduced, and delivered for introduction, into interstate commerce; and (3) defendant, in introducing the misbranded device into interstate commerce, acted with the intent to defraud and mislead. Defendant agrees that the maximum penalties for each count of shipping misbranded medical devices in interstate commerce are as follows:

a.	Maximum fine	$500,000 or the greater of twice the gross gain or twice the gross loss
b.	Maximum term of probation	5 years
c.	Mandatory special assessment	$400
d.	Restitution	Up to the amount of the loss

2. Defendant agrees that it is guilty of the offenses to which it will plead guilty, and

agrees that the following facts are true:

Defendant is a corporation engaged in the development, manufacture, and distribution of medical devices and is located in Menlo Park, California. Defendant developed, manufactures, and distributes a medical device known as the Ancure Endograft System ("Ancure Device"). Following its acquisition in November 1997, defendant was a wholly owned subsidiary of Guidant Corporation, a corporation engaged in the development, manufacture, and distribution of medical devices, whose principal offices are located in Indianapolis, Indiana.

Defendant designed the Ancure Device for use in the treatment of abdominal aortic aneurysms, a potentially life threatening condition. An abdominal aortic aneurysm is a weak area that develops in the wall of the aorta, the artery that brings blood flow from the heart through the abdomen to the rest of the body. The Ancure Device sold by defendant has two primary parts. One part is a delivery catheter used to place the vascular endograft into the aorta. The delivery catheter is inserted into a blood vessel through an incision made in the patient's leg. The second part of the Ancure Device is a vascular endograft that is placed in the patient's aorta using a delivery system to prevent an aneurysm from rupturing. The vascular endograft consists of a woven fabric graft with an attachment system that includes hooks. The vascular endograft is designed to remain in the patient's aorta permanently after being implanted. The delivery catheter is designed to be removed from the patient after the vascular endograft is implanted.

Defendant developed and marketed the Ancure Device as an alternative to the traditional and more invasive treatment for abdominal aortic aneurysms: surgery in which the patient's abdomen is cut open to enable the physician to reach the aorta. The use of the Ancure Device was indicated at the time of its approval for commercial marketing by the United States Food & Drug Administration ("FDA") for the endovascular treatment of infrarenal abdominal or aorto-iliac aneurysms in patients having (i) adequate iliac/femoral access; (ii) infrarenal non-aneurysmal neck length of at least 15 millimeters and a diameter of no greater than 26 millimeters; (iii) distal segment lengths of at least 20 millimeters and diameters no greater than 13.4 millimeters; and (iv) morphology suitable for endovascular repair. The Ancure Device was and is a medical device within the meaning of the Federal Food, Drug, and Cosmetic Act

("FD&C Act"). Each Ancure Device sold by defendant costs approximately $10,000.

The FDA was, and is, the agency responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law. Toward this end, FDA, pursuant to its statutory mandate, regulates and monitors the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices and makes information available to the public and to physicians about medical devices.

In order to legally distribute a medical device in interstate commerce, defendant was required to include adequate instructions for use unless expressly exempted from this requirement. In the case of the Ancure Device, defendant was required to provide instructions for use, approved by FDA, as part of the labeling of the Ancure Device. These instructions explain to doctors how to use the Ancure Device for the indicated medical purposes, including any methods of administration, relevant hazards, contraindications and precautions. Changes to the instructions for use that affect the safety or effectiveness of a medical device may not be made without the approval of FDA.

Defendant could not legally sell the Ancure Device in the United States without the approval of FDA. In order to be approved by FDA, the premarket approval application ("PMA") was required to include the results of clinical studies conducted upon humans that demonstrated that the device was safe and effective for its intended use(s). In addition, defendant was and is required to submit a PMA Supplement for review and approval by FDA before making a change that affects the safety or effectiveness of the Ancure Device. Among the changes that require a PMA Supplement are any new indications for use of the Ancure Device and changes in the components or physical layout of the Ancure Device that affect its safety or effectiveness.

FDA first approved the Ancure Device for commercial sale in the United States on September 30, 1999. On the same day, FDA also approved a competing product for commercial sale in the United States. The competing product approved by FDA also was designed to treat abdominal aortic aneurysms by the insertion of an endograft into the aorta. From the first day the

Ancure Device was approved for commercial sale in the United States, defendant faced competition for market share.

Before FDA approved the Ancure Device for commercial sale, defendant learned from physicians during clinical trials that the delivery system of the Ancure Device was perceived as more difficult to use than the competing product. Certain of defendant's employees viewed the complexity of the delivery system of the Ancure Device as the company's primary marketing challenge. Certain officials of defendant believed that if the Ancure Device could not be successfully deployed in a significant number of cases, it had the potential to harm marketing efforts and discourage physician customers from choosing the Ancure Device.

After defendant began selling the Ancure Device in the United States, the company became aware of various malfunctions (as defined in the relevant regulations) that occurred in the delivery system of the Ancure Device. In some instances, physicians were unable to implant the Ancure Device due to a problem in using the delivery system of the Ancure Device. In other instances, physicians were able to implant the Ancure Device but could not do so in a way that was consistent with the approved instructions for use. Some of the malfunctions resulted in the delivery system of the Ancure Device becoming improperly lodged in the body. In these latter cases, some of the patients had to undergo traditional open surgical repair to remove the delivery system of the Ancure Device and correct the aneurysm. The malfunctions in this Plea Agreement relate only to the delivery system of the Ancure Device, and do not relate to the Ancure Device after it has been implanted.

Some sales representatives of defendant provided information to doctors regarding a procedure that involved breaking or cutting the handle of the Ancure Device when the delivery system became lodged in a patient and could not be removed without resorting to traditional open surgical repair ("Handle Breaking Technique"). The Handle Breaking Technique was devised in part by a sales representative of defendant. The Handle Breaking Technique involved breaking or cutting the handle of the delivery system and removing the catheters housed within the delivery system of the Ancure Device individually from the patient's body.

At the time defendant first provided information to doctors regarding the Handle

Breaking Technique through its sales representatives, the technique had not been tested; doctors had not been trained on its use; sales representatives who described the technique to doctors during surgery had not been trained by the company on its use; the instructions for use had not been altered to include the Handle Breaking Technique; and defendant had failed to seek prior approval of FDA concerning the use of the Handle Breaking Technique. On or about January 26, 2000, the Handle Breaking Technique was utilized in an operation unsuccessfully. The patient in that operation ultimately died. This incident caused a group of defendant's employees to conclude that the safety of the Handle Breaking Technique was uncertain; that the Handle Breaking Technique required testing and validation; and, if it were to be used, that the Handle Breaking Technique should be submitted to FDA.

Defendant became aware that physicians continued to use the Handle Breaking Technique and that its sales representatives continued to provide information to doctors regarding the Handle Breaking Technique during surgical procedures where it was believed necessary to avoid standard open surgical repair. During the times relevant to the Information filed in this case, the Handle Breaking Technique was not submitted to FDA for its review and approval and was not included in the instructions for use.

Defendant was required by law to report to FDA within 30 days whenever it received or otherwise became aware of information from any source that reasonably suggested that the Ancure Device (1) may have caused or contributed to a death or serious injury; or (2) had malfunctioned and the device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. These reports are known as Medical Device Reports (MDRs). FDA makes MDRs available to physicians and other members of the public so that they can be aware of recurring malfunctions and other risks concerning medical devices. Pursuant to federal regulation, submission of an MDR does not constitute an admission by a manufacturer that a device caused or contributed to the event that is reported.

Pursuant to federal law, a medical device causes or contributes to a death or serious injury (as defined in the relevant regulations) whenever a death or serious injury was, or may have been, attributed to a medical device, or that a medical device was or may have been a factor in a death

or serious injury, including events occurring as a result of failure, malfunction, improper or inadequate design, manufacture, labeling, or user error.

Accordingly, pursuant to the relevant federal law, a patient undergoing a surgical procedure using the Ancure Device suffered a serious injury (as defined in the relevant regulations) when he or she (1) experienced an injury or illness that was life-threatening; (2) experienced an injury or an illness that resulted in permanent impairment of a body function or permanent damage to body structure; or (3) experienced an injury or illness that required medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Evidence of actual causation is not required for there to be an obligation to file an MDR report.

Where the use of the delivery system of the Ancure Device was unsuccessful and the result was a conversion to traditional open surgical repair, it was reportable as an MDR. Patients who experienced an unsuccessful endovascular repair attempt, and as a result, underwent conversion to traditional open surgical repair, could have increased complications, such as arterial trauma, renal insufficiency, and bleeding.

During this time period, when the deployment of the Ancure Device required additional surgical procedures, it was reportable as an MDR. Defendant promoted the device as an alternative for patients who would otherwise undergo traditional open surgical repair.

As a condition of FDA approval, defendant initially was required to have sales representatives present to observe each surgical procedure in which the Ancure Device was implanted, or an implant was attempted. There was a company policy to require any employee with knowledge of allegations of death, serious injury, or malfunctions that were caused, or may have been caused, by the Ancure Device to report such information to defendant. These allegations were to be reported to defendant's Customer Service Department.

After FDA approved the Ancure Device for commercial sale in the United States, defendant received information about the number and type of malfunctions (as defined in the relevant regulations) through complaints by physicians, reports from the company's own sales representatives, and from other company employees. The incidences of recurring malfunctions

were repeatedly tabulated, distributed to certain officials within defendant, and discussed internally.

Defendant received information that some of these malfunctions (i) may have caused or contributed to patients' deaths and serious injuries or (ii) would be likely to cause a death or serious injury if the malfunction were to recur. Defendant did not provide information to FDA of these malfunctions by filing MDRs, or otherwise, and did not seek FDA approval to modify its instructions for use to reflect this information.

In or about July 2000, FDA conducted an inspection of defendant's headquarters in Menlo Park, California. During the inspection, the inspector requested a list of all complaints regarding difficulties of the catheter's jacket to retract properly during surgical use of the delivery system of the Ancure Device. Defendant provided the FDA inspector with a list of 55 complaints. In fact, as defendant well knew, there were more than 200 incidents that constituted complaints (as defined in the relevant regulations) concerning this malfunction that had occurred between October 1999 and April 2000 alone. Defendant knowingly and intentionally misled FDA about the frequency with which the delivery system of the Ancure Device malfunctioned in this manner.

In or about October 2000, seven anonymous employees (the "Anonymous Seven") sent a letter to FDA and to an official of defendant's parent corporation describing ethical, legal and safety concerns with the Ancure Device. Among other such concerns, the letter stated:

a. defendant had conducted incomplete testing and analysis on currently recommended procedures;

b. defendant had recommended the use of the device in a manner that was outside the directions for use approved by FDA;

c. The jacket retraction failure mode, which involved the failure of the sheath of the Ancure Device to retract as intended, had a corresponding complaint rate of approximately 20 percent;

d. defendant had failed to report to FDA product changes that affected safety and efficacy as legally required; and

e. defendant failed to submit MDRs to FDA as legally required.

The letter listed numerous circumstances that were not reported and specifically named two surgeries during which the Ancure Device malfunctioned that had resulted in death.

Following the receipt of this letter, an investigation authorized by the defendant concluded that, at certain times relevant to the Information, defendant had serious quality system regulation violations, incomplete and untimely complaint handling and documentation, incomplete MDR reporting, inadequate corrective and preventative action activities, incomplete record keeping and poor traceability practices, and was significantly out of compliance with FDA regulations and its own internal policies.

From September 30, 1999 to March 16, 2001, defendant introduced approximately 7,632 Devices into interstate commerce.

Between September 30, 1999 and March 16, 2001, defendant filed 172 MDRs for the delivery system of the Ancure Device.

On or about March 23, 2001, defendant disclosed to FDA the existence of approximately 2,628 additional MDRs concerning the delivery system of the Ancure Device that had not been previously reported to FDA, as required by law. Among those 2,628 MDRs that had not been timely filed were 12 deaths and 57 conversions to traditional open surgical repair. Defendant suspended commercial sale of the Ancure Device as of March 16, 2001.

On or about March 23, 2001, defendant informed FDA that it had failed to seek prior approval to amend its instructions for use to include the Handle Breaking Technique as legally required.

On or about November 3, 1999, defendant, with the intent to defraud or mislead, shipped an Ancure device from Menlo Park, California, to Baltimore, Maryland.

On or about November 13, 1999, defendant, with the intent to defraud or mislead, shipped an Ancure device from Menlo Park, California, to Phoenix, Arizona.

On or about February 16, 2000, defendant, with the intent to defraud or mislead, shipped an Ancure device from Menlo Park, California, to Minneapolis, Minnesota.

On or about May 17, 2000, defendant, with the intent to defraud or mislead, shipped an

Ancure device from Menlo Park, California, to Fort Myers, Florida.

On or about May 17, 2000, defendant, with the intent to defraud or mislead, shipped an Ancure, device from Menlo Park, California, to Norfolk, Virginia.

On or about May 11, 2000, defendant, with the intent to defraud or mislead, shipped an Ancure device from Menlo Park, California, to Richmond, Indiana.

On or about July 12, 2000, defendant, with the intent to defraud or mislead, shipped an Ancure device from Menlo Park, California, to St. Louis, Missouri.

On or about September 6, 2000, defendant, with the intent to defraud or mislead, shipped an Ancure device from Menlo Park, California, to Fargo, North Dakota.

On or about September 22, 2000, defendant, with the intent to defraud or mislead, shipped an Ancure device from Menlo Park, California, to Cleveland, Ohio.

3. Defendant agrees to give up all rights that it would have if it chose to proceed to trial, including the rights to a jury trial with the assistance of an attorney; to confront and cross-examine government witnesses; to move to suppress evidence or raise any other Fourth or Fifth Amendment claims; to any further discovery from the government; and to pursue any affirmative defenses and present evidence.

4. Defendant agrees to give up its right to appeal its convictions, the judgment, and orders of the Court. Defendant also agrees to waive any right it may have to appeal its sentence.

5. Defendant agrees not to file any collateral attack on its convictions or sentence, including a petition under 28 U.S.C. § 2255, at any time in the future after it is sentenced, except for a claim that its constitutional right to the effective assistance of counsel was violated.

6. Defendant agrees not to ask the Court to withdraw its guilty plea at any time after it is entered, unless the Court declines to accept the sentence agreed to by the parties. Defendant agrees that the government may withdraw from this agreement if the Court does not accept the agreed upon sentence set out below.

7. Defendant agrees that it will make a good faith effort to pay any fine, forfeiture or restitution it is ordered to pay. After sentencing, defendant will, upon request of the Court, the government, or the U.S. Probation Office, release any of funds and property under its control in

order to pay any fine, forfeiture, or restitution. Defendant agrees to pay the special assessment at the time of sentencing.

8. In addition to any fine, defendant agrees to forfeit to the United States within ten days after sentencing and voluntarily a sum of ten million, nine hundred thousand dollars ($10,900,000), pursuant to 18 U.S.C. § 981. The defendant agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of this sum to the United States. These steps include but are not limited to making the sum available to the United States after the imposition of sentence, as directed by the government. Defendant agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets.

9. Defendant agrees that an appropriate disposition of this case is as follows: defendant shall, in addition to the $10.9 million in forfeiture described in paragraph 8 above, pay a criminal fine of thirty-two and a half million ($32.5 million), pursuant to Chapter Eight of the United States Sentencing Guidelines, for the 10 felony violations specified in the Information. This will result in a total sum of forty-three point four million dollars ($43.4 million) to be paid in accordance with the commitments made within this criminal plea agreement. In addition, in connection with the settlement of this matter, defendant has agreed to pay a civil settlement of forty-nine million dollars ($49 million) to the United States as set forth in the settlement agreement on this date. The criminal fine shall be payable by defendant within 10 days of the day that it is sentenced, in the manner directed by the government. The parties agree that, pursuant to U.S.S.G. § 8D1.1, a sentence of probation would not be appropriate and that there shall be no organizational probation imposed. In addition, the parties agree that no restitution shall be imposed pursuant to 18 U.S.C. § 3663 in that resolving any potential claims would unduly complicate the sentencing process and is most appropriately determined in this instance by the civil justice system.

10. Defendant and its parent corporation agree to cooperate with the government before and after it is sentenced. Each of the obligations sets forth in this paragraph shall apply equally to Defendant's parent corporation, except as to paragraph c. The cooperation will include, but will not be limited to, the following:

a. Except as provided in subparagraph 10(c), defendant will, upon reasonable notice and without requiring service of process, take all steps within its power to make available for interviews or testimony any current employees, officers, or directors of defendant or its parent corporation or parent corporation's wholly owned subsidiaries;

b. Except as provided in subparagraph 10(c), defendant will provide all documents and other materials created on or before May 1, 2001 asked for by the government without requiring service of process;

c. Defendant and the government have a common interest in a prompt and fair resolution of the investigation. Accordingly, defendant will not object, including asserting any privilege against the government, to the government's access to interviews, testimony, or providing documents that relate to, concern, or are associated in any way with the Ancure Device between June 1, 1999 and March 23, 2001, as well as interview memoranda created between January 1, 2001 through May 7, 2001. The government will maintain the confidentiality of these materials and will not disclose them to any third party, except to the extent that disclosure is required by law or would be in furtherance of the government's discharge of its duties and responsibilities, as the government may decide in its sole discretion; and

d. Defendant will withdraw from and not participate in any existing joint defense agreement or common interest agreement that pertain to the subject matter of the investigation. Defendant will not initiate contacts with former employees designated by the government without prior approval of the government and, if contacted by such designated individuals, will notify the government of the fact and the substance of such contacts.

As an alternative to the remedies set forth in paragraphs 11 and 12 of this agreement, if the U.S. Attorney's Office determines in the exercise of its reasonable discretion that these obligations of cooperation have not been met, defendant agrees to pay the costs of the

government's investigation between November 1, 2000, and the date of this Agreement. Defendant's obligations of cooperation under this agreement shall cease either upon five years from the date of the execution of this agreement or upon the conclusion of any proceedings that may arise from the investigation, whichever is later.

11. Defendant agrees not to commit or attempt to commit any crimes before sentence is imposed; intentionally provide false information or testimony to the Court, the Probation Office, or the government; or fail to comply with any of the other promises it has made in this Agreement. Defendant agrees that, if it fails to comply with any promises it has made in this Agreement, including but not limited to payment of the $10.9 million forfeiture amount, the $32.5 million criminal fine, and the $49 million civil settlement amount as described in Paragraphs 8 and 9 above then the government will be released from all of its promises, but defendant will not be released from its guilty plea.

12. If defendant is prosecuted after failing to comply with any promises it has made in this Agreement, then (a) defendant agrees that any statements made by its or its parent corporation's employees, officers or directors to any law enforcement or other government agency or in Court, whether or not made pursuant to the cooperation provisions of this Agreement, may be used in any way; (b) defendant waives any and all claims under the United States Constitution, Rule 11(e)(6) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal statute or rule, to suppress or restrict the use of my statements, or any leads derived from those statements; and (c) defendant waives any defense to any prosecution that it is barred by a statute of limitations, if the limitations period has run between the date of this Agreement and the date it is indicted.

13. Defendant agrees that this Agreement and the Settlement Agreement entered on the same date contains all of the promises and agreements between it and the government, and it will not claim otherwise in the future.

14. Except to the extent specifically noted, defendant agrees that this Agreement binds the U.S. Department of Justice and U.S. Attorney's Office for the Northern District of California only, and does not bind any other federal, state, or local agency.

15. Defendant and the government agree to waive their rights to have the Probation Department prepare a Presentence Report. Defendant and the government will request that the Court accept defendant's pleas of guilty and impose sentence on an expedited schedule as early as the date of arraignment, under the provisions of Federal Rule of Criminal Procedure 32(b)(1), U.S.S.G. § 6A1.1, and Local Criminal Rule 32-1(b).

The Government's Promises

15. Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the government agrees that the appropriate disposition of the case is as set forth in paragraph 9.

16. The government agrees not to file or seek any additional charges against defendant or any affiliates, subsidiaries, or parent corporations that could be filed as a result of the investigation that led to the pending information or that are related to the conduct described in the pending information.

17. The government agrees not to use any statements made by defendant pursuant to this Agreement against defendant or any affiliates, subsidiaries, or parent corporations, in or in connection with any legal proceeding, whether criminal, civil, or administrative, unless defendant fails to comply with any promises in this agreement. The government may, however, provide defendant's statements in any federal criminal proceeding. The government may also tell the Court and the U.S. Probation Department about the full extent of the defendant's criminal activities in connection with the calculation of the Sentencing Guidelines.

Defendant's Affirmations

18. Defendant confirms that it has had adequate time to discuss this case, the evidence, and this Agreement with its attorneys, and that they have provided it with all the legal advice requested.

19. Defendant confirms that while its representatives considered signing this Agreement and, at the time its representatives signed it, its representatives were not under the influence of any alcohol, drug, or medicine.

20. Defendant confirms that its decision to enter a guilty plea is made knowing the charges that have been brought against it, any possible defenses, and the benefits and possible

detriments of proceeding to trial. Defendant also confirms that its decision to plead guilty is made voluntarily, and no one coerced or threatened it to enter into this agreement.

I am the authorized representative of defendant, as well as the authorized representative of defendant's parent corporation with respect to paragraphs 10, 12 and 20 of this agreement, and in that capacity, I have read this agreement and carefully reviewed every part of it with the attorneys of defendant. Pursuant to a valid corporate resolution by the Board of Directors (a copy of which is attached to this agreement), I have been authorized to enter into this agreement on the behalf of defendant and its parent corporation. The representations contained in this agreement are true to the best of our knowledge and belief.

Dated: _____

_____
Authorized Representative
ENDOVASCULAR TECHNOLOGIES, INC. and its Parent Corporation

KEVIN V. RYAN
United States Attorney

Dated: _____

_____
MATTHEW J. JACOBS
Assistant United States Attorney

_____
DOUGLAS W. STEARN
Trial Attorney
Office of Consumer Litigation

We have fully explained to our client all the rights that a criminal defendant has and all the terms of this Agreement. In our opinion, our client understands all the terms of this Agreement and all the rights it is giving up by pleading guilty, and, based on the information now known to us, its decision to plead guilty is knowing and voluntary.

Dated: _____

_____
PETER S. SPIVACK
Attorney for Defendant

_____
ROBERT BREAKSTONE
Attorney for Defendant