IN THE UNITED STATES DISTRICT COURT EASTERN DISTRICT OF ARKANSAS

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TRACY SPONER	NOV 07 2012
Plaintiff,) JAMES W. McCORMACK, CLERK) By:
vs. HOWMEDICA OSTEONICS))) CASE NO.: <u>4:12-CV-</u> 701 DPM
CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS	This case assigned to District Judga Marshall and to Magistrate Rearney
Defendant.	and to Magistration to Kearney

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, TRACY SPONER, ("Plaintiff"), by and through the undersigned counsel, and brings this Complaint against Defendant, Howmedica Osteonics Corporation, and alleges as follows:

1. This is an action for damages relating to Defendant's development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "The Rejuvenate System" (hereinafter "Rejuvenate" or "Defective Device").

PARTIES, JURISDICTION AND VENUE

- 2. Plaintiff, Tracy Sponer, is a resident of North Little Rock, Pulaski County, Arkansas.
- 3. Defendant, Howmedica Osteonics Corporation, (hereinafter "HOWMEDICA"), d/b/a STRYKER ORTHOPAEDICS, is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, New Jersey 07430 and conducts business throughout the United States.

- 4. This Honorable Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The amount in controversy exceeds \$75,000 exclusive of interests and costs, and this is an action by an individual Plaintiff against a Defendant with its principal place of business in another state.
- 5. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

PLAINTIFF SPCIFIC ALLEGATIONS

- 6. Defendant's placed the Defective Device into the stream of interstate commerce and it was implanted in Plaintiff Tracy Sponer on September 6, 2011 at Arkansas Surgical Hospital, 5201 Northshore Drive, North Little Rock, Arkansas 72118 by Dr. William Hefley.
- 7. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff Tracy Sponer has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.
- 8. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff Tracy Sponer required a painful hip revision surgery. Her hip revision surgery was performed on September 18, 2012 at Arkansas Surgical Hospital, 5201 Northshore Drive, North Little Rock, Arkansas 72118 by Dr. William Hefley.

THE STRYKER REJUVENATE HISTORY

- 9. At all times material hereto, Defendant Stryker/Howmedica (hereinafter referred to collectively as "Defendant") developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name "The Rejuvenate System" (hereinafter "Rejuvenate System" or "Defective Device"), either directly or indirectly, to members of the general public throughout the United States, including to Plaintiff, Tracy Sponer.
- 10. On June 3, 2008, Defendant received FDA clearance to sell its Rejuvenate System in the United States.
- 11. In February 2009, Stryker released its Rejuvenate Modular Primary Hip System, the latest evolution in the Company's OmniFit and Secure-Fit Hip systems, which was approved for market by the FDA on June 3, 2008. The Rejuvenate Modular hip is an extension of the Stryker Modular Hip, which was approved for market by the FDA on September 13, 2007.
- 12. The Rejuvenate System is a modular hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis.
- 13. Unlike most prosthetic hip implants, the Rejuvenate System is an artificial hip replacement device consisting of two basic components: a chrome cobalt modular neck that is inserted into a titanium femoral stem. The System can be used with any number of bearing surface components comprised of the ball or artificial femoral head and an acetabular cup or socket.
- 14. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron. Their alloy was designed and patented by

Defendant and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants. The Defendant claims in its promotional materials for the Rejuvenate system that their alloy is both stronger and less rigid than other titanium alloys. It also claims that the particular titanium alloy has been tested and proven by Defendant to resist the effects of corrosion and fretting.

- 15. According to Stryker's materials, the Rejuvenate Modular Primary Hip System was developed to optimize anatomic restoration by providing options that offer enhanced stability, proven modularity and intra-operative flexibility. With a wide range of femoral stem and neck combinations and an extensive range of length, version and offset, the Rejuvenate Modular Primary Hip System was marketed to enable surgeons to better personalize the implant to a patient's unique anatomy.
- 16. The system is comprised of separate femoral stem and neck components and offers a variety of sizing options intra-operatively. The benefit, according to Stryker, was that by allowing the surgeon to independently manage leg length, neck version, and femoral offset, the system provides surgeons the ability to better personalize the biomechanics of a patient's hip replacement.
- 17. The Rejuvenate System combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with a plasma sprayed coating of commercially pure Ti and PureFix HA for the stem and CoCr for the neck. Stryker claims that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.
- 18. Despite Stryker's claims, this material combination has been reported to cause corrosion. Since the 1980's medical and scientific literature has reported corrosion to be a problem when Ti and CoCr have been used at modular junctions. In its marketing and sale of the

device, Stryker represented and warranted that its proprietary materials alleviate this problem.

19. On July 6, 2012 the FDA posted notice that Stryker initiated a voluntary recall of the Rejuvenate and ABG II modular neck stems.

URGENT SAFETY NOTICES AND RECALLS

- 20. In April, 2012, Defendant issued an Urgent Field Safety Notice to surgeons and hospitals in the United States.
- 21. In this notice, Defendant acknowledged that it had received reports of device failure due to heavy metal contamination. The Notice specifically referred to failures at the taper neck junction between the neck and stem due to corrosion and fretting.
- 22. This corrosion and fretting was exactly the same failure mechanism that Defendant had warranted would not occur because of the Rejuvenate's design and composition. It was also exactly the same failure mechanism that the medical and scientific community had been studying and documenting in modular device design since the 1980's.
- 23. The Notice went on to describe symptoms and findings identical to those experienced by Plaintiff.
- 24. Among those specifically mentioned in the Notice were tissue necrosis, metallosis, adverse soft tissue reaction, and pseudotumor formation.
- 25. Almost immediately following the Notice, Defendant issued a voluntary recall of the Stryker Rejuvenate and ABGII in Canada. In the recall notice, Defendant stated that it was amending the Instructions for Use for the device to include warnings that Defendant was on notice of the issues described in the Notice above.
- 26. Finally, on July 6, 2012, Defendant issued a voluntary recall of all Stryker Rejuvenate and ABG II stems. As part of the recall notice, Defendant once again cited reports of

device failure due to heavy metal fretting and corrosion.

THE FEDERAL REQUIREMENTS

- 27. Federal regulation states "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." See 21 CFR §7.3(g).
- 28. Federal regulation states: "Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." See 21 CFR §7.3 (m).
- 29. Federal regulation states: "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR §7.3 (m).
- 30. The classification of the product withdrawals and corrections of the Defendant's devices (described above) as Class II Recalls by the FDA confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.
- 31. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

- 32. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.
- 33. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).
- Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

- 35. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR §803.52.
- 36. Pursuant to federal regulation, manufacturers must report to FDA in 5 business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR §803.53.
- 37. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.
- 38. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also

meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

- 39. Pursuant to federal regulation, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."
- 40. Specifically, it is believed that with respect to the Rejuvenate System, Defendant failed to timely report adverse events, failed to timely conduct failure investigations and analysis, failed to timely report any and all information concerning product failures and corrections, failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification, failed to conduct necessary design validation, and sold a misbranded and adulterated product.

CAUSES OF ACTION

COUNT ONE STRICT PRODUCTS LIABILITY DEFECTIVE MANUFACTURE ARK. CODE ANN. § 4-86-102

- 41. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.
- 42. At all times material hereto, the Defendant was the manufacturer, designer, distributor, seller, and/or supplier of the Stryker Rejuvenate hip implant device.
- 43. The Stryker Rejuvenate devices manufactured, sold, distributed, supplied, and/or placed in the stream of commerce by the Defendant were defective in their manufacture and construction when they left the hands of the Defendant in that they deviated from product specifications and/or applicable federal requirements for these medical devices and posed a serious risk of injury and/or death.
- 44. Defendant knew or reasonably should have known that the Stryker Rejuvenate hip implant device, as manufactured or constructed, was defective and posed an unreasonable risk of harm to individuals, including Plaintiff, who used the Stryker Rejuvenate hip implant device as intended by Defendant.
- As a direct and proximate result of the defective manufacture or construction of the Defendants Stryker Rejuvenate device and Plaintiffs use of the defective Stryker Rejuvenate device as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendant and/or the Defendants failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

46. Plaintiff contends that the conduct of the Defendant is attended by circumstances of fraud, malice, or willful and wanton conduct, and constitutes a flagrant disregard for human life so as to warrant the imposition of exemplary damages.

COUNT TWO STRICT PRODUCTS LIABILITY DESIGN DEFECT ARK. CODE ANN. § 4-86-102

- 47. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.
- 48. The Stryker Rejuvenate devices as manufactured and supplied by Defendant were defective in design and formulation in that, when they left the hands of the Defendant, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary customer would expect and/or failed to comply with federal requirements for these medical devices.
- 49. The foreseeable risks associated with the design or formulation of the Stryker Rejuvenate device includes, but is not limited to, the fact that the design or formulation of the Stryker Rejuvenate device is more dangerous than a reasonably prudent consumer would expect when used in its intended manner and/or it failed to comply with federal requirements.
- 50. As a direct and proximate result of the defective design of the Defendants Stryker Rejuvenate device and Plaintiffs use of the defective Stryker Rejuvenate device as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendant and/or the Defendants failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

51. Plaintiff contends that the conduct of the Defendant is attended by circumstances of fraud, malice, or willful and wanton conduct, and constitutes a flagrant disregard for human life so as to warrant the imposition of exemplary damages.

COUNT THREE STRICT PRODUCTS LIABILITY FAILURE TO WARN ARK. CODE ANN. § 4-86-102

- 52. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.
- 53. At all times material hereto, the Defendant was the manufacturer, designer, distributor, seller, and/or supplier of the Stryker Rejuvenate hip implant device and sold the Stryker Rejuvenate device to patients knowing they would then be implanted in patients in need of a hip prosthesis.
- 54. The Stryker Rejuvenate device was expected to, and did, reach the Plaintiff without substantial change or adjustment in its condition as designed, manufactured, and sold by the Defendant.
- 55. The Stryker Rejuvenate device as designed, developed, tested, manufactured, marketed, sold, and/or placed in the stream of commerce by Defendant was in a dangerous and defective condition when it left the hands of the Defendant and posed a threat to any user of the device.
- 56. Plaintiff was and is in the class of persons that Defendant actually considered, or should have considered, to be subject to the harm caused by the defective nature of the Stryker Rejuvenate device.

- 57. The Stryker Rejuvenate device was implanted and used in the manner for which it was intended. Plaintiff's use of the Stryker Rejuvenate device as intended by Defendant resulted in severe physical and emotional and other injuries to the Plaintiff.
- 58. Defendant knew or should have known that the Stryker Rejuvenate device as designed, developed, tested, manufactured, marketed, sold, and/or placed in the stream of commerce by Defendant was in a dangerous and defective condition when it left the hands of the Defendant and posed a threat to any user of the device.
- 59. Defendant failed to provide adequate and timely warnings or instructions regarding the Stryker Rejuvenate device and its known defects.
- 60. As a direct and proximate result of the Defendants failure to warn Plaintiff of the dangerous condition of the Stryker Rejuvenate device and Plaintiff's use of the defective Stryker Rejuvenate device as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendant and/or the Defendants failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
- 61. Plaintiff contends that the conduct of the Defendant is attended by circumstances of fraud, malice, or willful and wanton conduct, and constitutes a flagrant disregard for human life so as to warrant the imposition of exemplary damages.

COUNT FOUR NEGLIGENCE AND WANTONNESS

- 62. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.
- 63. Defendant had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the Stryker Rejuvenate devices into the stream of commerce, including

a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events as well as a duty to comply with federal requirements.

- 64. Defendant had an obligation to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Stryker Rejuvenate devices, and otherwise distributing the Stryker Rejuvenate devices.
- 65. Defendants acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendant to civil liability for all damages arising therefrom.
- 66. Plaintiff, as a purchaser of Stryker Rejuvenate device, is within the class of persons that the statutes and regulations previously described herein are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.
- 67. Defendant failed to exercise ordinary care and/or was negligent and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Stryker Rejuvenate devices into interstate commerce because Defendant knew or should have known that these products caused significant bodily harm and were not safe for use by consumers, and/or through their failure to comply with federal requirements.
- 68. Despite the fact that Defendant knew or should have known that the Stryker Rejuvenate devices posed a serious risk of bodily harm to consumers, Defendant continued to manufacture and market the Stryker Rejuvenate devices for use by consumers and/or continued to fail to comply with federal requirements.

- 69. Defendant knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants failure to exercise ordinary care as described above, including the failure to comply with federal requirements.
- 70. As a direct and proximate result of Defendants negligence and/or wantonness, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
- 71. Plaintiff contends that the conduct of the Defendant as described above, including, but not limited to, its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Stryker Rejuvenate devices when Defendant knew or should have known of the serious health risks these devices created and/or the failure to comply with federal requirements, is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, and constitutes a conscious, reckless and flagrant disregard for human life, which warrants the imposition of exemplary damages.

COUNT FIVE BREACH OF EXPRESS WARRANTY ARK. CODE ANN. § 4-2-313

- 72. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.
- 73. Defendant expressly warranted that the Stryker Rejuvenate device was a safe and effective orthopedic device for patients requiring a hip replacement.
- 74. The Stryker Rejuvenate device manufactured and sold by Defendant did not conform to these express representations because they caused serious injury to Plaintiff when used as recommended and directed.

75. As a direct and proximate result of Defendants breach of warranty, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT SIX BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESSFOR A SPECIFIC PURPOSE ARK. CODE ANN. § 4-2-313 and § 4-2-314

- 76. Plaintiff adopts and incorporates by reference all the foregoing language of this Complaint as if fully set forth herein and further states as follows.
- 77. At the time the Defendant designed, manufactured, marketed, sold, and distributed the Stryker Rejuvenate device for use by Plaintiff, Defendant knew of the use for which the Stryker Rejuvenate devices were intended and impliedly warranted these products to be of merchantable quality and safe for their particular use in that their design, manufacture, labeling, and marketing complied with all applicable federal requirements.
- 78. Plaintiff and/or her physician reasonably relied upon the skill and judgment of Defendant as to whether the Stryker Rejuvenate device was of merchantable quality and safe for its intended particular use and upon Defendants implied warranty as to such matters, including that they were in compliance with all federal requirements.
- 79. Contrary to such implied warranties, Stryker's Rejuvenate device was not of merchantable quality or safe for their particular intended use because the products was defective as described above, and/or failed to comply with federal requirements.
- 80. As a direct and proximate result of Defendants breach of warranties, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant as follows:

- a. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars (\$75,000.00);
- b. For an award of punitive or exemplary damages against Defendants;
- c. For reasonable attorney fees and costs;
- d. For pre-judgment interest; and
- e. For such further and other relief this Court deems just and equitable.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable with the maximum number of jurors permitted by law.

Respectfully Submitted this 6th day of November 2012,

Annesley H. DeGaris

AL Bar No.: ASB-9182-A63A

Douglas A. Dellaccio

AL Bar No. ASB-4578-L75D

Cory, Watson, Crowder & DeGaris, P.C.

2131 Magnolia Avenue, Suite 200

Birmingham, AL 35205

Telephone: 205-328-2200 Facsimile: 205-324-7896

E-mail: <u>adegaris@cwcd.com</u>

ddellaccio@cwcd.com

Attorneys for Plaintiff

OF COUNSEL

Michael Rainwater

AR State Bar No.: 1979234

Stephen Holt

AR State Bar No.: 1996171 Rainwater, Holt & Sexton, P.A.

6315 Ranch Drive

Little Rock, Arkansas 72223 Telephone: 501-868-2910 JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil coversheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS Tracy Sponer (b) County of Residence of First Listed Plaintiff Pulaski County, Arka								ersey		
(EXCEPT IN U.S. PLAINTIFF CASES)				(IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.				ON OF		
(c) Attorneys (Firm Name,	Address, and Telephone Number	r)		Attorneys (If Know	w <i>n)</i>					
Annesley H. DeGaris & Douglas A. Dellaccio - Cory, Watson, Crowder & DeGaris, 2131 Magnolia Ave., Birmingham, AL 35205; 205-328-2200										
II. BASIS OF JURISD	ICTION (Place an "X" i	in One Box Only)		ITIZENSHIP OF		NCIPA	L PARTIES			
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2 U.S. Government Defendant	■ 4 Diversity (Indicate Citizenshi	ip of Parties in Item III)	Citiz	en of Another State	O 2	D 2	Incorporated and P of Business In A		5	X 5
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IV. NATURE OF SUIT										
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☐ 160 Stockholders' Suits ☐ 190 Other Contract	☐ 355 Motor Vehicle Product Liability	371 Truth in Lending380 Other Personal		?0 Labor/Mgmt. Relations I0 Railway Labor Act			C/DIWW (405(g)) Title XVI	☐ 890 Other S ☐ 891 Agricul		ctions
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REAL PROPERTY 210 Land Condemnation	CIVIL RIGHTS 3 440 Other Civil Rights	PRISONER PETITIO ☐ 510 Motions to Vacat		Security Act	_		AL TAX SUITS s (U.S. Plaintiff	☐ 899 Admini	strative Pr	
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290 All Other Real Property	445 Amer. w/Disabilities -	540 Mandamus & Otl		2 Naturalization Applicat	tion					
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VI. CAUSE OF ACTIO	1 28 USC Section		re filing (Do not cite jurisdictional	l statute	s unless d	iversity):			
	Plaintiff injured a	s a direct result of	Defenda	ants' defective hip	impla	nt devi	ce.			
VII. REQUESTED IN COMPLAINT:	CHECK IF THIS UNDER F.R.C.P.	IS A CLASS ACTION 23	N D	EMAND \$			HECK YES only URY DEMAND:		complaii No	nt:
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