IN THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF IOWA
EASTERN DIVISION

KEVIN SAWVEL, individually and on behalf of all similarly situated persons, Plaintiffs, vs. SORIN GROUP DEUTSCHLAND GMBH and SORIN GROUP USA, INC. Defendants.	**CASE NO. 6:17-cv-2056** **COMPLAINT AND JURY DEMAND**

COMES NOW Plaintiff Kevin Sawvel, individually and on behalf of all similarly situated persons, by and through his undersigned attorneys, and alleges the following upon information and belief, except for those allegations pertaining to Plaintiff which are based on personal knowledge.

NATURE OF THE ACTION

1. Plaintiff Kevin Sawvel (hereinafter "Plaintiff") brings this action individually and on behalf of all persons similarly situated in the State of Iowa who were unknowingly exposed to a potentially fatal bacteria during open heart surgery.

2. Plaintiff and the Class were exposed to M. Chimaera and/or M. Abscessus, subspecies of nontuberculous mycobacterium (collectively referred to as "NTM" herein), through a Sorin 3T Heater-Cooler System manufactured by the Defendants and used to regulate their blood temperature during surgeries at the University of Iowa Hospitals and Clinics ("UIHC").

3. As further described below, Defendants knew or should have known that design and/or manufacturing defects in their Sorin 3T Heater-Cooler System causes bacterial

colonization to which patients are exposed during surgery, thus posing a significant risk of bodily injury or death.

4. Through this action, Plaintiff and the Class seek medical monitoring to screen for NTM infections, and pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, et seq., seek a declaration that the Sorin 3T Heater-Cooler System was and is defective and unsafe for its intended use.

JURISIDCTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties, 28 USCS § 1332(a)(2). Plaintiff is a resident of the State of Iowa. Defendant Sorin Group Deutschland Gmbh is a foreign corporation headquartered in Munich, Germany. Defendant Sorin Group USA Inc. is a Delaware corporation with its principal place of business in Arvada, Colorado. Personal jurisdiction exists over Defendant Sorin Group Deutschland Gmbh in the United States due to the general and specific contacts it maintained in the United States at all times material to this action. The amount in controversy exceeds $75,000.00.

6. This Court additionally has subject matter over this action pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d). There are more than 1,500 putative class members, who are or were citizens of the State of Iowa at the time of their exposure, and Defendants are citizens of another state and/or foreign country. The Class Members' claims exceed $5 million dollars, exclusive of interests and costs.

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391, as a substantial part of the events and/or omissions giving rise to the Plaintiffs' claim emanated from activities within this jurisdiction and Defendants do substantial business within this jurisdiction.

PARTIES

8. Plaintiff and proposed Class Representative Kevin Sawvel is an individual who at all material times resided in Gilbertville, Iowa. Plaintiff had open heart surgery at UIHC on June 19, 2016, and was exposed to NTM as a result of the use of the Sorin 3T Heater-Cooler System during his surgery.

9. Defendant Sorin Group Deutschland Gmbh is a foreign corporation headquartered in Munich, Germany.

10. Defendant Sorin Group USA Inc. is a Delaware corporation with its principal place of business in Arvada, Colorado. Sorin Group Deutschland Gmbh and Sorin Group USA, Inc. designed, manufactured, marketed, and sold the Sorin 3T Heater-Cooler Systems used in Plaintiff and Class Members' surgeries.

FACTUAL ALLEGATIONS

A. UIHC Patient Exposure to Deadly Bacteria

11. On or about February 2, 2016, UIHC announced that approximately 1,500 of its patients who had major heart, lung, or liver surgeries between January 1, 2012 and January 22, 2016 had been exposed to a rare and potentially fatal bacterium via Sorin 3T Heater-Cooler Systems used to regulate blood temperature.

12. In addition to announcements to the public, UIHC reported that it sent letters to individual patients which informed them of the exposure and advised them to follow up with their physicians.

B. The Fatal Bacteria

13. The bacteria at issue are *M. Chimaera* and *M. Abscessus*. The bacteria are subspecies of nontuberculous mycobactermium ("NTM")[1], which occur naturally in the environment and rarely causes illness. However, NTM poses a unique health risk to those with compromised immune systems, and in particular those who have undergone invasive surgical procedures. Because NTM is a slow growing bacterium, it generally takes anywhere from two weeks to five years before manifestation of an NTM infection, which most commonly results in pulmonary or cardiovascular disease. The recommended monitoring period after exposure is at least five years.

14. Symptoms of an NTM infection are very general and may include any combination of the following: fever, pain, redness, heat or pus around the surgical incision, night sweats, joint pain, muscle pain, and fatigue.

15. Because NTM symptoms are non-specific and manifestation may take several weeks to several years, a patient will most likely fail to link the infection to his or his prior heart surgery, particularly as more time elapses between surgery and initial symptomatology.

16. The diagnosis of an NTM infection requires targeted culturing, molecular diagnostic testing, and/or other screening processes not performed unless physicians are acutely aware of NTM exposure.

17. Most NTM infections are naturally resistant to common antibiotics. In order to overcome drug resistance, it is often necessary to take several different antibiotics at the same

[1] Discovery in this action may reveal that different strands of NTM, or other bacteria types altogether, have been transmitted to Plaintiff and putative Class Members through the same mechanism. As such, Plaintiff reserves his right to amend his Complaint with specific facts learned through discovery.

time. Depending on the severity of the infection, treatment may be needed for as long as two years.

18. While an NTM infection diagnosed early on may be successfully treated with a series of antibiotics, there is a significant risk of death in cases diagnosed late and in individuals with considerably weakened immune systems.

19. Upon information and belief, at least one individual who underwent open heart surgery at UIHC died as a result of an NTM infection.

20. The risk of NTM transmission with the 3T System is not unique to UIHC. For example, in October and November 2015, two Pennsylvania hospitals notified approximately 3,600 patients who underwent open heart surgeries between October 1, 2011 and November 5, 2015 of their exposure to NTM through use of the 3T System. To date, there have been eleven confirmed NTM infections in Pennsylvania which have resulted in five deaths.

C. Medical Devices Identified as the Infection Source

21. The CDC has affirmatively linked the NTM infection risk at UIHC to the Sorin 3T Heater-Cooler System used to regulate patient blood temperature during cardiovascular surgeries.

22. Heater-cooler devices work by aerosolizing temperature controlled water. When the water used in the reservoir of the device contains even trace levels of NTM, the bacteria colonizes, and patients are exposed to the bacteria that are aerosolized through the device's exhaust vent.

23. The airborne transmission of NTM from contaminated heater-cooler units was recognized as a patient risk throughout Europe as early as 2011.

24. A Rapid Risk Assessment released by the European Centre for Disease Prevention and Control ("ECDC") in April 2015 notes that invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011.[2]

25. A public health investigation in Switzerland included microbiological examinations of environmental samples that identified *M. Chimaera* (a strand of NTM) contamination in heater-cooler units, including water samples from the units. Air sampling cultures were positive for *M. Chimaera* when the units were running, but negative when they were turned off.[3]

26. In July 2015, an article was published in the Journal of Clinical Infectious Diseases following patients in Europe who contracted NTM. The article concluded that the epidemiological and microbiological features of the prolonged outbreak in Europe provided evidence of the airborne transmission of *M. Chimaera* from contaminated heater-cooler units.

27. On October 15, 2015, the Food and Drug Administration ("FDA") issued a Safety Communication which noted that between January 2010 and August 2015, the agency received thirty-two Medical Device Reports of patient infections associated with heater-cooler device contamination, eight in the U.S, and the remaining twenty-four predominantly from Western Europe.

28. On October 21, 2015, the Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication intended to raise awareness among health

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[2] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at http:/lecdc.europa.eu/en/publications/Publications/mycobacterium-chimaerainfection-associated-with-heater- cooler-units-rapid-risk-assessment-30-April-20 15.pdf (last accessed on January 26, 2016).

[3] *Id.*

departments, healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

29. On June 1, 2016, the FDA issued an updated Safety Communication which advised that there may be a higher risk of patient infection associated with surgeries that introduced a prosthetic product/material [e.g., heart valve, graft, LVAD], or heart transplants when the 3T was used and recommended that healthcare providers determine a method for patient follow-up and establish patient surveillance in cases of potential exposure, per the recommendations in CDC's Interim Guide for the Identification of Possible Cases of Nontuberculous Mycobacterium Infections Associated with Exposure to Heater-Cooler Units.

30. In October 2016, the FDA issued an updated Safety Communication which reported clusters of patients infected with *M. chimaera* were located in Iowa. Specifically, the Centers for Disease Control and Prevention (CDC) and National Jewish Health performed whole genome sequencing on clinical isolates from infected patients and samples taken from the 3T devices from hospitals representing geographically distinct regions within the U.S. (Pennsylvania and Iowa) where clusters of patient infections with *M. chimaera* were identified. Each of the isolates tested were associated with devices manufactured before September 2014. Samples of the water drained from the 3T devices and air samples collected while the devices were in operation were also tested. The results obtained strongly suggest that the tested 3T devices had a common source of *M. chimaera* contamination.

D. Defendants' 3T Heater-Cooler System

31. The Sorin 3T Heater-Cooler Systems ("3T Systems") used at UIHC during the relevant time periods were designed, manufactured, marketed, and sold by Defendants to UIHC in Iowa.

32. On July 15, 2015, the FDA issued a Class 2 Recall of the 3T System because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

33. The recall directed customers to follow the new cleaning and disinfection procedures outlined in a Field Safety Notice issued by Defendants on June 15, 2015.

34. According to the June 2015 Field Safety Notice, its hygiene concept was "enhanced" by introducing the following modifications:

i. The use of filtered tap water when filling the device;

ii. Instead of three different procedures (every five days, every 2 weeks and every 3 months), only two different procedures (every 7 days and every 14 days) to make disinfection easier;

iii. The option to use peracetic acid instead of chloride solution;

iv. H202 in low dose for preservation;

v. All external tubing, bottles and buckets were to be included in the disinfection process;

vi. The use of polyethylene tubing that meets national drinking water standards; and

vii. That unused heater-coolers must be disinfected bi-weekly.

35. However, a month prior to the recall, in May 2015, Defendants determined that devices that had not been maintained according to the manufacturer's instructions for use ("IFUs") for a long period of time required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

36. Upon information and belief, Defendants knew or should have known that design and/or manufacturing defects in their 3T System renders it prone to bacterial colonization, regardless of the cleaning and disinfection procedures used.

37. The FDA recently raised significant questions about the safety and efficacy of the Sorin 3T System.

38. On December 29, 2015, the FDA sent Defendants a warning letter advising the company that its 3T Systems were subject to refusal of admission into the U.S. until it resolved several FDA violations, including the FDA's determination that the 3T Heater-Cooler Systems were adulterated[4] and misbranded and lacked requisite safety validation for several design changes to both the device itself as well as a series of revised disinfection instructions.

39. In the letter, the FDA identified various design change orders dating back to December 11, 2012 which had never been submitted to the FDA for approval.

40. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, which had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

E. UIHC Respond to the Crisis

41. Shortly after learning of the association between NTM infection and its 3T Heater-Cooler Systems, UIHC created online resources for patients exposed to the bacteria.

42. According to UIHC's website, medical services are currently being provided to exposed patients at no cost.[5]

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[4] Under the Federal Food, Drug and Cosmetic Act, a medical device is "adulterated" if the methods used in, or the facilities or controls used for his manufacture, packing, storage or installation are not in conformity with current good manufacturing practice requirements of the Quality System regulation

[5] https://uihc.org/news/potential-infection-risk-major-heart-and-lung-surgeries (last accessed May 22, 2017).

43. It is unknown how long UIHC intends to continue offering these services. It is likewise unknown if there are any limitations to the services being offered by UIHC which may inhibit the early detection of NTM infections.

CLASS ACTION ALLEGATIONS

44. The Class claims all derive directly from a single course of conduct by the Defendants. The Defendants engaged in uniform and standardized conduct toward the Class. They did not differentiate, in degree of care or candor, their actions or inactions among individual Class members. The objective facts are the same for all Class members. Within each Claim for Relief, the same legal standards under Iowa and/or federal law govern. Accordingly, Plaintiff brings this lawsuit as a class action on his own behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Fed. R. Civ. P. 23. This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions.

Class Definition

45. Plaintiff seeks to certify a class defined as follows:

> All individuals residing in the State of Iowa who underwent open heart surgery at the University of Iowa Hospitals and Clinics between January 1, 2012 and January 22, 2016 and who are currently asymptomatic for nontuberculous mycobacterium (or "NTM") infection. Claims for actual injury from an NTM infection are excluded from the claims brought in this class action.

46. Plaintiff seeks to certify the above defined Class for all causes of action alleged herein.

47. The prerequisites to maintaining a class action under Fed. R. Civ. P. 23(a) and (b) are met for the following reasons:

a. **Numerosity:** Upon information and belief, Plaintiff states that there are at least 1,500 individuals who underwent open heart surgery during the relevant time periods. Therefore, the proposed Class is so numerous that joinder of all individual members is impractical.

b. **Commonality:** Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members.

Among the questions of law and fact common to Plaintiff and Class Members are:

i. Whether and the degree to which they were exposed to NTM during their surgeries;

ii. Whether they were exposed to NTM at rates higher than, or through a more dangerous manner than, the general population;

iii. Whether the 3T System is the source of their NTM exposure;

iv. Whether the Defendant knew or should have known of their NTM exposure;

v. Whether their exposure to NTM was caused by the negligence of the Defendant;

vi. Whether the 3T System is defectively designed;

vii. Whether safer alternative designs for the 3T System existed which could have prevented the colonization and aerosolization of bacteria;

viii. Whether the 3T System used in their surgeries contained manufacturing defects;

ix. Whether the 3T System is unsafe for its intended use; and

x. Whether the Defendants are legally responsible for implementing and maintaining a medical monitoring fund to provide NTM screening.

c. **Typicality:** Plaintiffs' claim is typical of the claims of Class Members because they each underwent surgeries at UIHC during the time period in which the allegedly defective medical devices were used. Plaintiff alleges that his exposure to NTM occurred in substantially the same way. As such, the claims or defenses of the representative parties are typical of the claims or defenses of the class.

d. **Adequacy of Representation:** Plaintiff will fairly and adequately protect the interests of Class Members. Plaintiff have retained counsel competent and experienced in complex class action litigation and with adequate resources to assure the interests of the Class will not be harmed. The named Plaintiff is typically situated and have no conflict of interest with the Class as a whole.

e. **Class Action Maintainable under Rule 23(b)(2):** A class action is appropriate because common questions of law and fact predominate over any individual questions affecting only individual members. Class treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single form simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. No difficulties are likely to be encountered in the management of this class action that would preclude its maintenance as a class action, and no superior alternative exists for the fair and efficient adjudication of this controversy. Without a class action, the Defendant will remain free from responsibility for

exposing at least 1,500 patients to a potentially deadly bacterium and Class Members, who have limited resources, will either be forced to fund their own medical screening or forgo the necessary screening due to financial constraints.

f. **Class Action Maintainable Under Rule 23(b)(3):** By negligently exposing Plaintiff and Class Members to NTM, the Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making the implementation and maintenance of a medical monitoring fund and declaratory relief the appropriate remedies for the Class.

g. **Ascertainability:** The Class Members are ascertainable as UIHC can identify every single class member from their contemporaneously kept medical records. Accordingly, nothing more than a ministerial act on the part of non-party UIHC will be necessary to ascertain all potential Class Members.

TOLLING OF THE STATUTE OF LIMITATIONS

Discovery Rule

48. Under Iowa law, the discovery rule tolls the statute of limitations when a plaintiff, due to facts or circumstances not within his or his control, is unable to discover his injury and its cause within the prescribed time period.

49. Under the discovery rule, the statute of limitations begins to run when a plaintiff knows, or in the exercise of reasonable diligence should have known (i) that he or she has been injured, and (ii) that his or her injury was caused by the conduct of another.

50. Prior to UIHC's announcements and correspondence advising that Plaintiff and Class Members may have been exposed to NTM, Plaintiff was wholly unaware of both his

exposures to NTM and the fact that his exposures may have been caused by a defective medical device.

51. Any applicable statute of limitation has therefore been tolled by Plaintiff and Class Members' lack of knowledge of the facts alleged herein prior to February 2016.

COUNT I – MEDICAL MONITORING

52. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

53. The latency period for the manifestation of an NTM infection is estimated to be between anywhere from two weeks to five years after exposure.

54. Plaintiff and Class Members have been exposed to NTM at rates higher than, or in a substantially more dangerous manner than, the general population. Plaintiffs' exposure levels are therefore substantial in nature.

55. When NTM is transmitted by the method described above, namely airborne transmission from a contaminated medical device to an individual undergoing invasive surgery, it is widely acknowledged as a dangerous and potentially life-threatening bacteria.

56. Plaintiff and the Class Members' exposure to NTM was caused by Defendants.

57. Defendants are negligent for the following reasons:

a. Failing to conduct adequate safety and efficacy testing before seeking to have the 3T System put into the stream of commerce;

b. Failing to notify the FDA of design change orders to the 3T System;

c. Supplying "validation" studies to the FDA which failed to demonstrate the safety and efficacy of cleaning and disinfection procedures for the 3T System;

d. Failing to warn Plaintiff and Class Members of the potential for bacterial colonization and patient exposure to such bacteria;

e. Designing the 3T System in such a way that it is prone to bacterial colonization and aerosolization; and

f. Failing to ensure proper workmanship, materials and labeling for the 3T System.

58. Plaintiff and the Class Members' exposure to NTM was proximately caused by Defendants' negligence as described herein.

59. Monitoring procedures exist that make the detection of NTM infections possible.

60. NTM infections are capable of early detection by way of existing scientific methods including, but not limited to, targeted culturing and DNA sequencing of invasive samples (e.g., blood, pus, tissue biopsy, or implanted prosthetic material).

61. Because NTM screening is not conducted in the absence of exposure to NTM, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require specialized screening not within the purview of routine medical exams.

62. The prescribed monitoring regime is reasonably necessary according to contemporary scientific principles in order to provide for early diagnosis of NTM infections leading to benefits in treatment, management, rehabilitation and prevention or mitigation of long term health consequences, including death.

COUNT II – DECLARATORY RELIEF PURUSANT TO 28 U.S.C. § 2201, *ET SEQ.*

63. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

64. Pursuant to 28 U.S.C. § 2201, a court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

65. Declaratory relief is intended to minimize "the danger of avoidable loss and unnecessary accrual of damages." 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2751 (3d ed. 1998).

66. Plaintiff alleges that the Sorin 3T Heater-Cooler System is defective in that it is prone to bacterial colonization which may be transmitted to patients during surgery.

67. There are actual controversies between the Defendant and Plaintiff, including prospective Class members, concerning: (i) whether the 3T System is defective, (ii) whether the Defendants knew, or should have known, of defects in their 3T System, and (iii) whether the Defendants failed to adequately warn of the risk of bacterial colonization in its 3T System.

68. The declaratory relief requested herein will generate common answers that will settle the controversy related to the alleged defects in the Sorin 3T System. There is an economy to resolving this issue as it has the potential to eliminate the need for continued and repeated litigation regarding alleged defects in this medical device.

69. Plaintiff therefore seeks a declaration that the Sorin 3T Heater-Cooler System is defective, and that the Defendants must expeditiously notify the Class of such defects.

PRAYER FOR RELIEF

Plaintiff, on behalf of himself and all others similarly situated, requests the Court to enter judgment against the Defendants as follows:

A. An order certifying the proposed Class and designating Plaintiff as the named representative of the Class, and designating the undersigned as Class Counsel;

B. A declaration that the Sorin 3T Heater-Cooler System is defective and unsafe for its intended use;

C. A declaration that the Defendants are financially responsible for implementing and maintaining a fund for the medical monitoring of Plaintiff and Class Members;

D. An award to Plaintiff and Class Members of damages, costs and disbursements in this action, including reasonable attorneys' fees, as permitted by law;

E. An award of pre-judgment and post-judgment interest, as provided bylaw;

F. Leave to amend this Complaint to conform to the evidence produced at trial; and

G. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues so triable.

Dated: September 25, 2017 SHINDLER ANDERSON GOPLERUD & WEESE PC

/s/ J. Barton Goplerud

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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet 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

KEVIN SAWVEL, individually and on behalf of all simlarly situated persons

(b) County of Residence of First Listed Plaintiff Blackhawk County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

See Attachment

DEFENDANTS

SORIN Group Deutschland GMBH and SORIN GROUP USA, INC.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable Sat TV
- ☐ 850 Securities Commodities Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:

Brief description of cause:
Products Liability

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE DOCKET NUMBER

DATE 9-25-17

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

ATTORNEY'S REPRESENTING PLAINTIFFS

J. Barton Goplerud, AT0002983
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