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7 8	Attorneys for Plaintiff Colibri Heart Valve LLC	
9	UNITED STATES DISTRICT COURT	
10	CENTRAL DISTRICT OF CALIFORNIA	
11	SOUTHERN DIVISION	
12		
13	Colibri Heart Valve LLC,	Case No.
14	Plaintiff,	COMPLAINT FOR PATENT
15	V.	INFRINGEMENT
16	Medtronic CoreValve LLC; and Medtronic plc,	DEMAND FOR JURY TRIAL
17	Defendants.	
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Plaintiff Colibri Heart Valve LLC ("Colibri" or "Plaintiff"), by and through the undersigned counsel, brings this action against Defendants Medtronic CoreValve LLC and Medtronic plc (together, "Medtronic") alleging as follows:

INTRODUCTION

- 1. This is an action by Colibri against Medtronic for infringement of U.S. Patent Nos. 9,125,739 ("the '739 patent") and 8,900,294 ("the '294 patent"), which claim groundbreaking artificial heart valves and methods for using them.
- 2. Heart disease is the leading cause of death in the U.S. Over five million people in the U.S. are diagnosed with heart valve disease annually. Sometimes heart valve disease can be treated with medication, or the diseased heart valve can be repaired through surgery. In severe cases, however, the heart valve is so diseased that it cannot be treated by medication or repaired, and must be replaced with an artificial heart valve. Over 100,000 defective heart valves are replaced in the U.S. each year.
- 3. Inventors Drs. David Paniagua and R. David Fish, leading interventional cardiologists and innovators in the field of cardiovascular intervention, have worked hard to address the need for treatment options for patients who suffer from debilitating heart valve disease and require a new heart valve. Their work has resulted in the discovery and development of artificial heart valves and treatment methodologies that could offer patients an opportunity to receive a less invasive heart valve therapy. Drs. Paniagua and Fish co-founded Colibri, and their work became the basis for Colibri's patented inventions.
- 4. Colibri's life-saving inventions include a patented, self-expanding heart valve device that includes cross-linked biological tissue and a delivery system that can be guided through a patient's artery to the heart where it is positioned and used to replace diseased valves. The patented device and method of controlled release, which includes making a small incision through which a thin, flexible tube is inserted into the artery, is far less invasive than open heart surgery. The



controlled release capability permits a surgeon to recover the patented heart valve device during deployment. For its innovation, Colibri was awarded the '294 Patent and the '739 Patent, among others.

5. Medtronic manufactures and sells self-expanding heart valves and delivery systems, including transcatheter aortic valve replacement (TAVR) products that infringe Colibri's patents. The Medtronic TAVR devices go by a variety of names, including CoreValve, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ (the "CoreValve Products"). Medtronic's infringing CoreValve Products include cross-linked biological tissue and a delivery system that can be guided through a patient's artery to the heart where they are positioned and used to replace diseased valves, as taught by Colibri's patents, and are inserted using Colibri's patented method of controlled release.

THE PARTIES

- 6. Plaintiff Colibri Heart Valve LLC is a corporation organized under the laws of Delaware, with its principal place of business at 486 South Pierce Avenue, Suite B, Louisville, Colorado 80027.
- 7. Colibri is a medical device company that researches and develops novel heart valve technologies. Colibri was founded in 2010 by Drs. Paniagua and Fish.
- 8. On information and belief, Defendant Medtronic CoreValve LLC is a corporation organized under the laws of Delaware, with a principal place of business at 1851 East Deere Avenue, Santa Ana, California 92705.
- 9. On information and belief, Defendant Medtronic plc is a public limited company organized under the laws of Ireland, with a principal place of business and international headquarters in Dublin, Ireland. Medtronic plc is the successor entity to Medtronic, Inc., and operates in the United States and elsewhere through Medtronic CoreValve LLC, among other entities. Medtronic plc and Medtronic CoreValve LLC are collectively referred to herein as "Medtronic."



JURISDICTION AND VENUE

This Court has subject matter jurisdiction pursuant to 28 U.S.C.

§§ 1331 and 1338(a).

10.

11. Personal jurisdiction over Medtronic is proper because it continuously and systematically conducts business in Santa Ana, California, including the manufacture and sale of the infringing CoreValve Products.

12. Venue is proper in the Central District of California under 28 U.S.C. §§ 1391(b) and 1400(b) because Medtronic resides in this District and a substantial part of the events and omissions giving rise to the claims at issue occurred here, including the manufacture and sale of the infringing CoreValve Products.

FACTUAL BACKGROUND

Background of Colibri

- 13. As noted above, Colibri was co-founded by Drs. Paniagua and Fish. Dr. Paniagua's education and training includes completion of his Interventional Cardiology Fellowship at the Texas Heart Institute/Baylor College of Medicine Program, and training in interventional cardiology at the Texas Heart Institute. Amongst Dr. Paniagua's significant achievements, he is credited with having conducted the first retrograde percutaneous aortic heart valve implant in a human in the world.
- 14. Like Dr. Paniagua, Dr. Fish is a leading interventional cardiologist and an innovator in the field of cardiovascular intervention. Among other accomplishments, Dr. Fish received the Physician-Scientist Award from the National Heart Lung & Blood Institute of the National Institutes of Health. Dr. Fish served as Director of Interventional Cardiology Research and Education at the Texas Heart Institute, and subsequently became Director of the Heart Valve Center there. In 2015, he became the inaugural chair of the Multidisciplinary Heart Team at the Baylor St. Luke's Medical Center.



15. Drs. Paniagua and Fish have worked since at least January 4, 2002, on developing and improving Colibri's transcatheter aortic valve implantation system (the "Colibri TAVI System") into today's pre-mounted, pre-crimped, and pre-loaded heart valve that is sterilized and ready for use.



The Colibri TAVI System

16. A goal of any artificial heart valve is to deliver as much blood and oxygen to the patient as possible. Colibri has demonstrated in its early human feasibility study that its valves can deliver approximately twice as much oxygenated blood to patients as all of the existing artificial heart valves currently being implanted in patients.

Colibri Meets with Medtronic

17. On or about May 6, 2014, under the protection of a Non-Disclosure Agreement, Colibri's President and CEO Joseph Horn gave a presentation about Colibri's heart valve accomplishments to several persons whom Mr. Horn understood to be Medtronic's marketing director and senior clinical program manager. Among other things, Mr. Horn discussed the successful implementation of Colibri's TAVI System in a patient. Mr. Horn also provided details about



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