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7 Attorneys for Plaintiff  
Colibri Heart Valve LLC

9 UNITED STATES DISTRICT COURT  
10 CENTRAL DISTRICT OF CALIFORNIA  
11 SOUTHERN DIVISION

13 Colibri Heart Valve LLC,  
14 Plaintiff,  
15 v.  
16 Medtronic CoreValve LLC; and  
Medtronic plc,  
17 Defendants.

Case No.

**COMPLAINT FOR PATENT  
INFRINGEMENT**

**DEMAND FOR JURY TRIAL**

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1 Plaintiff Colibri Heart Valve LLC (“Colibri” or “Plaintiff”), by and through  
2 the undersigned counsel, brings this action against Defendants Medtronic  
3 CoreValve LLC and Medtronic plc (together, “Medtronic”) alleging as follows:

#### 4 **INTRODUCTION**

5 1. This is an action by Colibri against Medtronic for infringement of U.S.  
6 Patent Nos. 9,125,739 (“the ’739 patent”) and 8,900,294 (“the ’294 patent”), which  
7 claim groundbreaking artificial heart valves and methods for using them.

8 2. Heart disease is the leading cause of death in the U.S. Over five  
9 million people in the U.S. are diagnosed with heart valve disease annually.  
10 Sometimes heart valve disease can be treated with medication, or the diseased heart  
11 valve can be repaired through surgery. In severe cases, however, the heart valve is  
12 so diseased that it cannot be treated by medication or repaired, and must be replaced  
13 with an artificial heart valve. Over 100,000 defective heart valves are replaced in  
14 the U.S. each year.

15 3. Inventors Drs. David Paniagua and R. David Fish, leading  
16 interventional cardiologists and innovators in the field of cardiovascular  
17 intervention, have worked hard to address the need for treatment options for  
18 patients who suffer from debilitating heart valve disease and require a new heart  
19 valve. Their work has resulted in the discovery and development of artificial heart  
20 valves and treatment methodologies that could offer patients an opportunity to  
21 receive a less invasive heart valve therapy. Drs. Paniagua and Fish co-founded  
22 Colibri, and their work became the basis for Colibri’s patented inventions.

23 4. Colibri’s life-saving inventions include a patented, self-expanding  
24 heart valve device that includes cross-linked biological tissue and a delivery system  
25 that can be guided through a patient’s artery to the heart where it is positioned and  
26 used to replace diseased valves. The patented device and method of controlled  
27 release, which includes making a small incision through which a thin, flexible tube  
28 is inserted into the artery, is far less invasive than open heart surgery. The

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

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

### 13 **THE PARTIES**

14 6. Plaintiff Colibri Heart Valve LLC is a corporation organized under the  
15 laws of Delaware, with its principal place of business at 486 South Pierce Avenue,  
16 Suite B, Louisville, Colorado 80027.

17 7. Colibri is a medical device company that researches and develops  
18 novel heart valve technologies. Colibri was founded in 2010 by Drs. Paniagua and  
19 Fish.

20 8. On information and belief, Defendant Medtronic CoreValve LLC is a  
21 corporation organized under the laws of Delaware, with a principal place of  
22 business at 1851 East Deere Avenue, Santa Ana, California 92705.

23 9. On information and belief, Defendant Medtronic plc is a public limited  
24 company organized under the laws of Ireland, with a principal place of business and  
25 international headquarters in Dublin, Ireland. Medtronic plc is the successor entity  
26 to Medtronic, Inc., and operates in the United States and elsewhere through  
27 Medtronic CoreValve LLC, among other entities. Medtronic plc and Medtronic  
28 CoreValve LLC are collectively referred to herein as "Medtronic."

1 **JURISDICTION AND VENUE**

2 10. This Court has subject matter jurisdiction pursuant to 28 U.S.C.  
3 §§ 1331 and 1338(a).

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

7 12. Venue is proper in the Central District of California under 28 U.S.C.  
8 §§ 1391(b) and 1400(b) because Medtronic resides in this District and a substantial  
9 part of the events and omissions giving rise to the claims at issue occurred here,  
10 including the manufacture and sale of the infringing CoreValve Products.

11 **FACTUAL BACKGROUND**

12 **Background of Colibri**

13 13. As noted above, Colibri was co-founded by Drs. Paniagua and Fish.  
14 Dr. Paniagua’s education and training includes completion of his Interventional  
15 Cardiology Fellowship at the Texas Heart Institute/Baylor College of Medicine  
16 Program, and training in interventional cardiology at the Texas Heart  
17 Institute. Amongst Dr. Paniagua’s significant achievements, he is credited with  
18 having conducted the first retrograde percutaneous aortic heart valve implant in a  
19 human in the world.

20 14. Like Dr. Paniagua, Dr. Fish is a leading interventional cardiologist and  
21 an innovator in the field of cardiovascular intervention. Among other  
22 accomplishments, Dr. Fish received the Physician-Scientist Award from the  
23 National Heart Lung & Blood Institute of the National Institutes of Health.  
24 Dr. Fish served as Director of Interventional Cardiology Research and Education at  
25 the Texas Heart Institute, and subsequently became Director of the Heart Valve  
26 Center there. In 2015, he became the inaugural chair of the Multidisciplinary Heart  
27 Team at the Baylor St. Luke’s Medical Center.  
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1           15. Drs. Paniagua and Fish have worked since at least January 4, 2002, on  
2 developing and improving Colibri's transcatheter aortic valve implantation system  
3 (the "Colibri TAVI System") into today's pre-mounted, pre-crimped, and pre-  
4 loaded heart valve that is sterilized and ready for use.



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16           *The Colibri TAVI System*

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

22           **Colibri Meets with Medtronic**

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

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