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12					
13	UNITED STATES DISTRICT COURT				
14		DISTRICT OF		IA	
15	SOUTHERN DIVISION				
16					
17	Colibri Heart Valve LLC,	Cas	e No. 8:19-cv	-02351	
18	Plaintiff,			OR PATENT	
19	V.		FRINGEMEN		
20	Medtronic CoreValve LLC; and Medtronic plc,	DE.	MAND FOR	JURY TRIAL	
21	Defendants.				
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<ul><li>23</li><li>24</li></ul>					
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	COMPLAINT FOR PATENT INFRING	EMENT			

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

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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.

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**

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

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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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1	Colibri's proprietary heart valve products, delivery systems, and methods, including		
2	the patented Colibri TAVI system. In addition, on July 2, 2014, Colibri and		
3	Medtronic held a conference call that included discussion of Colibri's patent		
4	portfolio. More particularly, Mr. Horn, Eric Schauble (Colibri's Vice President of		
5	Business Development), and Colibri's outside patent counsel Mark Yaskanin,		
6	discussed Colibri's patent portfolio with a Medtronic employee in Business		
7	Development, and a Medtronic patent attorney. Among other topics, the		
8	participants discussed the recent allowance of a related Colibri patent application		
9	claiming a heart valve device with flared ends in a trumpet-like configuration, as		
0	well as other pending patent applications, including Colibri's then pending U.S.		
1	Patent Application Nos. 14/253,650 and 14/253,656 that correspond to Colibri's		
2	issued '739 and '294 patents, respectively.		
3	THE PATENTS-IN-SUIT		
4	The '739 Patent		
5	18. The '739 patent, entitled "Percutaneous Replacement Heart Valve and		
6	a Delivery and Implementation System," was issued by the United States Patent		
7	and Trademark Office on September 8, 2015. A true and correct copy of the '739		
8	patent is attached hereto as Exhibit 1.		
9	19. Colibri is the owner of the entire right, title, and interest in and to the		
20	'739 patent.		
21	20. Claim 1 of the '739 patent recites:		
22	1. An assembly to treat a native heart valve in a patient, the		
23	assembly for use in combination with a guidewire, the assembly		
24	comprising:		
25	a prosthetic heart valve including:		
26	a stent member having an inner channel, the stent member		
27	collapsible, expandable and configured for trans-luminal		
28	percutaneous delivery, wherein the stent member includes a		

tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and

- a valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means resides entirely within the inner channel of the stent member, and wherein no reinforcing members reside within the inner channel of the stent member;
- a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath, wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and wherein the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.

#### The '294 Patent

- 21. The '294 patent, entitled "Method of Controlled Release of a Percutaneous Replacement Heart Valve," was issued by the United States Patent and Trademark Office on December 2, 2014. A true and correct copy of the '294 patent is attached hereto as Exhibit 2.
- 22. Colibri is the owner of the entire right, title, and interest in and to the '294 patent.
  - 23. Claim 1 of the '294 patent recites:

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1. A method of controlled release of a percutaneous replacement heart valve at a location of a native heart valve in a patient, the method comprising:

obtaining a replacement heart valve device and a delivery and implantation system:

the replacement heart valve device including:

- a stent member that is collapsible, expandable and configured for percutaneous delivery; and
- a valve residing entirely within an inner channel of the stent member and attached to a proximal portion of the stent member, the valve including two to four individual leaflets made of fixed pericardial tissue;

the delivery and implantation system including:

- a pusher member and a moveable sheath, wherein the pusher member includes a guide wire lumen, and wherein the moveable sheath includes a lumen configured for receiving the pusher member;
- after the obtaining step, loading the replacement heart valve device into the lumen of the moveable sheath such that the replacement heart valve device is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath;
- after the loading step, advancing the delivery and implantation system transluminally over a guide wire within the patient to position the replacement heart valve device for deployment within the patient at the location of the native heart valve;

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after the advancing step, partially deploying a distal portion of the replacement heart valve device within the patient by pushing out the pusher member from the moveable sheath to expose the distal portion of the replacement heart valve device;

after the partially deploying step, restraining the replacement heart valve device so that it does not pop out and is held for controlled release, with a potential that the replacement heart valve device can be recovered if there is a problem with positioning; and

after the restraining step, recovering the distal portion of the replacement heart valve device within the moveable sheath that was exposed in order to address a problem with the position of the replacement heart valve device within the patient.

## MEDTRONIC'S INFRINGING PRODUCTS

24. Medtronic is the world's largest medical device company and makes the majority of its sales and profits from the U.S. healthcare system. Medtronic maintains over 350 locations in more than 150 countries, and has over 86,000 employees. The company was previously a U.S. corporation but in 2015, moved its headquarters to Ireland for tax purposes. Medtronic makes a variety of medical instruments or appliances, including products related to vessel sealing, lighted retractors, wound closure, and surgical stapling. Out of Medtronic's approximately \$30 billion in revenue, \$11.4 billion represents revenue from its Cardiac and Vascular Group. Medtronic makes four infringing transcatheter aortic valve replacement ("TAVR") products—CoreValve, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+.

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1	25. Like Colibri's patented technology, the CoreValve, CoreValve
2	Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems are each
3	comprised of a transcatheter aortic valve (or bioprosthesis) and a delivery catheter
4	system.
5	The Medtronic CoreValve System
6	26. Upon information and belief, Medtronic began commercial marketing
7	of the CoreValve System in 2014.
8	27. The Medtronic CoreValve System comprises a transcatheter aortic
9	valve (or bioprosthesis) and a delivery catheter system.
10	28. The CoreValve transcatheter aortic valve comprises three valve
11	leaflets, manufactured from porcine pericardium. Like Colibri's patented
12	technology, these leaflets are sutured onto a collapsible and expandable, multi-
13	level, radiopaque stent with flared ends in a trumpet-like configuration. The
14	CoreValve transcatheter aortic valve comes or came in at least four models/sizes,
15	including Models MCS-P4-23-AOA (23 mm; CoreValve Evolut), MCS-P3-26-
16	AOA (26 mm), MCSP3-29-AOA (29 mm), and MCS-P3-31-AOA (31 mm).
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The Medtronic CoreValve transcatheter aortic valve

29. Like Colibri's patented technology, the delivery catheter system deploys the valve. The delivery catheter system comprises a pusher member and a

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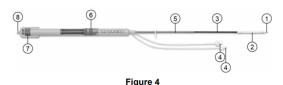
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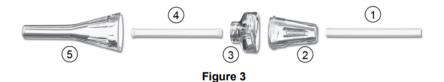
moveable sheath. It also comprises a deployment end and a handle. The deployment end has a tip and a capsule that covers and maintains the transcatheter aortic valve in a crimped position. The handle loads and deploys the valve. A macro slider on the handle opens and closes the capsule and micro knob to facilitate the placement of the transcatheter aortic valve.



- 1. Catheter tip
- 2. Capsule
- 3. Catheter shaft
- 4. Tube flush port
- AccuTrak™ stability layer
- 6. Macro slider
- 7. Micro knob
- 8. Luer-lock connection flush port

### The Medtronic CoreValve delivery catheter system

30. The compression loading system compresses the transcatheter aortic valve into the catheter.



- 1. Inflow tube (straight tube)
- 2. Outflow cone
- 3. Outflow cap
- 4. Outflow tube (tube with flared ends)
- 5. Inflow cone

## The Medtronic CoreValve compression loading system

31. Medtronic also provides instructional manuals and videos on how to use the CoreValve System. *See, e.g.*, CoreValve Manual; CoreValve Loading Video (with Audio), YouTube, https://youtu.be/tCtLqdCOdgc.

#### The Medtronic CoreValve Evolut R

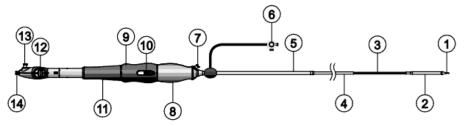
- 32. The CoreValve Evolut R System is Medtronic's second device in its TAVR product line. Upon information and belief, Medtronic began commercially marketing the CoreValve Evolut PRO System in the United States shortly after June 22, 2015.
- 33. The CoreValve Evolut R System comprises a CoreValve Evolut R transcatheter aortic valve (or bioprosthesis) and a delivery catheter system.
- 34. The CoreValve Evolut R transcatheter aortic valve comprises three valve leaflets, manufactured from porcine pericardium. Like Colibri's patented technology, these leaflets are sutured onto a collapsible and expandable, multilevel, radiopaque stent with flared ends in a trumpet-like configuration. The CoreValve Evolut R transcatheter aortic valve comes in at least four models/sizes, including Models EVOLUTR-23-US (23 mm), EVOLUTR-26-US (26 mm), EVOLUTR-29-US (29 mm), and EVOLUTR-34-US (34 mm).



#### The Medtronic CoreValve Evolut R transcatheter aortic valve

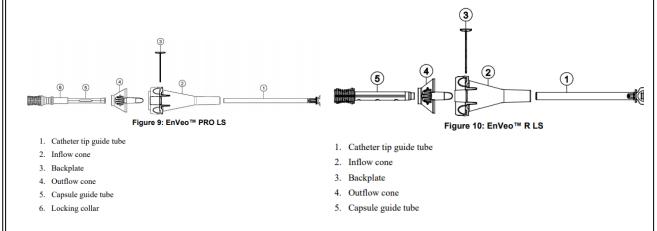
35. Like Colibri's patented technology, the delivery system catheter deploys the valve. The deployment system catheter comprises a pusher member and a moveable sheath. In addition, the delivery system catheter utilizes a catheter with an integrated handle that loads, deploys, and recaptures the transcatheter aortic valve. The CoreValve Evolut R catheter comes in two models. For each, the

deployment end of the system comprises a catheter tip and a capsule that covers and maintains the transcatheter aortic valve in a crimped position. The delivery system has a pusher member that includes a guidewire lumen and a moveable sheath with a lumen that enables the valve to be recaptured after partial deployment.



The Medtronic CoreValve Evolut R delivery catheter system

36. The loading system compresses the transcatheter aortic valve into the catheter. The loading system comes in two models.



The Medtronic CoreValve Evolut R loading systems

#### The Medtronic CoreValve Evolut PRO

37. Medtronic's CoreValve Evolut PRO System is its third TAVR product. Upon information and belief, Medtronic began commercially marketing the CoreValve Evolut PRO System in the United States shortly after March 20, 2017.

38. The Medtronic CoreValve Evolut PRO System comprises a CoreValve Evolut PRO transcatheter aortic valve and a delivery catheter system.

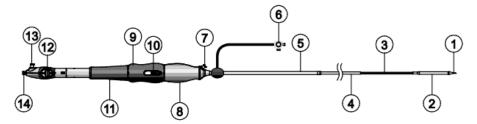
39. The CoreValve Evolut PRO transcatheter aortic valve comprises three valve leaflets, manufactured from porcine pericardium. Like Colibri's patented technology, these leaflets are sutured onto a collapsible and expandable, multilevel, radiopaque stent with flared ends in a trumpet-like configuration. The CoreValve Evolut PRO transcatheter aortic valve comes in at least three models/sizes, including Models EVOLUTPRO-23-US (23 mm), EVOLUTPRO-26-US (26 mm), and EVOLUTPRO-29-US (29 mm).



The Medtronic CoreValve Evolut PRO transcatheter aortic valve

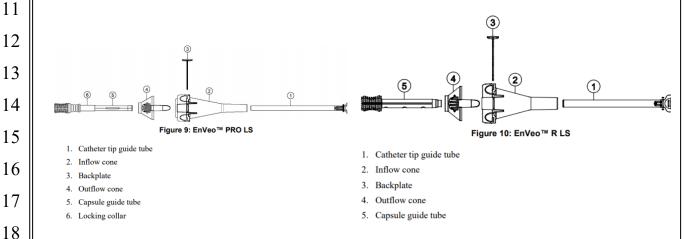
40. Like Colibri's patented technology, the CoreValve Evolut PRO delivery catheter system deploys the valve. The deployment system catheter comprises a pusher member and a moveable sheath. In addition, the delivery catheter system utilizes a catheter with an integrated handle that loads, deploys, and recaptures the transcatheter aortic valve. The CoreValve Evolut PRO catheter comes in two models. For each, the deployment end of the system comprises a catheter tip and a capsule that covers and maintains the transcatheter aortic valve in a crimped position. The delivery system has a pusher member that includes a

guidewire lumen and a moveable sheath with a lumen that enables the valve to be recaptured after partial deployment.



The Medtronic CoreValve Evolut PRO delivery catheter system

41. The loading system compresses the transcatheter aortic valve into the catheter. The loading system comes in two models.



The Medtronic CoreValve Evolut PRO loading systems

#### The Medtronic CoreValve Evolut PRO+

- 42. Medtronic's fourth iteration of its TAVR product line is called the CoreValve Evolut PRO+ System. Upon information and belief, Medtronic began commercially marketing the CoreValve Evolut PRO+ System in the United States shortly after September 19, 2019.
- 43. The CoreValve Evolut PRO+ comprises a CoreValve Evolut PRO+ transcatheter aortic valve and a delivery catheter system.

The CoreValve Evolut PRO+ transcatheter aortic valve comprises 44. three valve leaflets, manufactured from porcine pericardium. Upon information and belief, like Colibri's patented technology, these leaflets are sutured onto a collapsible and expandable, multi-level, radiopaque stent with flared ends in a trumpet-like configuration. The CoreValve Evolut PRO+ transcatheter aortic valve comes in at least four models/sizes, including Models EVPROPLUS-23US (23) mm), EVPROPLUS-26US (26 mm), EVPROPLUS-29US (29 mm), and EVPROPLUS-34US (34 mm).

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Evolut PRO+ 23 mm Valve

Model Number: **EVPROPLUS-23US** Size: 23 mm

Aortic annulus 17\*/18-20 mm



Evolut PRO+ 26 mm Valve

Model Number: EVPROPLUS-26US

Aortic annulus 20-23 mm

Size: 26 mm



Evolut PRO+ 29 mm Valve

Model Number: EVPROPLUS-29US

Size: 29 mm Aortic annulus

23-26 mm



Evolut PRO+ 34 mm Valve

Model Number: EVPROPLUS-34US

Size: 34 mm Aortic annulus 26-30 mm

The Medtronic CoreValve Evolut PRO+ transcatheter heart valve

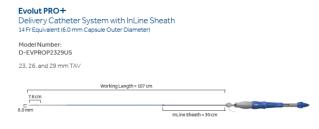
Like Colibri's patented technology, the Evolut PRO+ delivery catheter 45. system comprises a pusher member and a moveable sheath. The delivery catheter system deploys the valve:

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The Medtronic Evolut PRO+ Delivery Catheter Systems

46. The Evolut PRO+ Loading System compresses the transcatheter aortic valve into the catheter. This loading system comes in two models:





The Medtronic Evolut PRO+ Loading Systems

#### **CLAIM I**

## (Infringement of the '739 Patent)

- 47. Colibri repeats and realleges the foregoing allegations as if fully set forth herein.
  - 48. The '739 patent is valid and enforceable.
- 49. Medtronic has had actual notice of the '739 patent no later than the date of filing and service of this Complaint and prior to that was at least aware of the patent family from which the '739 patent would ultimately issue since May 6, 2014.
- 50. Each of the CoreValve, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems, including their use in accordance with the guidance and instructions that Medtronic provides for these products, infringes one or more claims of the '739 patent, including, without limitation, claim 1, either literally or under the doctrine of equivalents.
- 51. In violation of 35 U.S.C. § 271(a), Medtronic has been and is directly infringing the '739 patent, either literally or under the doctrine of equivalents, by making, using, selling, and/or offering to sell in the United States, and/or importing into the United States, without license or authority, the CoreValve, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems.
- 52. In violation of 35 U.S.C. § 271(b), Medtronic has been and is indirectly infringing the '739 patent by inducing infringement of this patent by

- 53. Medtronic's affirmative acts of making, selling, and offering to sell its services and/or products, or components thereof, cause the CoreValve, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems to be used in a manner that infringes the '739 patent. Medtronic further provides guidance and instruction to third parties to use the CoreValve, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems in their normal and customary way to infringe the '739 patent.
- 54. Medtronic specifically intends that surgeons and other third parties infringe the '739 patent. Medtronic performs the acts that constitute induced infringement with knowledge of the '739 patent and with knowledge or willful blindness that the induced acts would constitute infringement.
- 55. In violation of 35 U.S.C. § 271(c), Medtronic has been and is indirectly infringing the '739 patent by contributing to the infringement of this patent by others, such as surgeons, other medical professionals, and patients, in the United States. Medtronic has offered to sell and sell in the United States, and imported into the United States, the CoreValve, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems, which are a material part of the claimed invention of the '739 patent. Medtronic knows that the CoreValve, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems are especially made or especially adapted for use in an infringement of the '739 patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.
- 56. Medtronic has willfully infringed the '739 patent by deliberately and egregious engaging in acts of infringement on an ongoing basis with knowledge of Colibri's patent.

## **CLAIM II**

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# (Infringement of the '294 Patent)

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forth herein.

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Colibri repeats and realleges the foregoing allegations as if fully set

- 58. The '294 patent is valid and enforceable.
- 59. Medtronic has had actual notice of the '294 patent no later than the date of filing and service of this Complaint and prior to that was at least aware of the patent family from which the '294 patent would ultimately issue since May 6, 2014.
- 60. The use of each of the CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems, in accordance with the guidance and instructions that Medtronic provides for these products, infringes one or more claims of the '294 patent, including, without limitation, claim 1, either literally or under the doctrine of equivalents.
- In violation of 35 U.S.C. § 271(a), Medtronic has been and is directly infringing the '294 patent, either literally or under the doctrine of equivalents, by using, without license or authority, the CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems in the United States.
- In violation of 35 U.S.C. § 271(b), Medtronic has been and is indirectly infringing the '294 patent by inducing infringement of this patent by others, such as surgeons, other medical professionals, and patients, in the United States.
- Medtronic's affirmative acts of making, selling, and offering to sell its services and/or products, or components thereof, cause the CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems to be used in a manner that infringes the '294 patent. Medtronic further provides guidance and instruction to third parties to use the CoreValve Evolut R, CoreValve Evolut PRO,

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27 28 and CoreValve Evolut PRO+ Systems in their normal and customary way to infringe the '294 patent.

- 64. Medtronic specifically intends that surgeons and other third parties infringe the '294 patent. Medtronic performs the acts that constitute induced infringement with knowledge of the '294 patent and with knowledge or willful blindness that the induced acts would constitute infringement.
- In violation of 35 U.S.C. § 271(c), Medtronic has been and is indirectly infringing the '294 patent by contributing to the infringement of this patent by others, such as surgeons, other medical professionals, and patients, in the United States. Medtronic has made, offered to sell and sells in the United States, and imported into the United States, CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems, which are a material part of the claimed invention of the '294 patent. Medtronic knows that the CoreValve Evolut R, CoreValve Evolut PRO, and CoreValve Evolut PRO+ Systems are especially made or especially adapted for use in an infringement of the '294 patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.
- Medtronic has willfully infringed the '294 patent by deliberately and egregious engaging in acts of infringement on an ongoing basis with knowledge of Colibri's patent.

## PRAYER FOR RELIEF

WHEREFORE, Colibri respectfully requests that this Court enter judgment in its favor and grant the following relief against Medtronic as follows:

- Judgment that Medtronic infringed and continues to infringe the '739 A. patent;
- Judgment that Medtronic infringed and continues to infringe the '294 В. patent;
- C. Judgment that Medtronic's infringement was and is willful;

1 D. Award Colibri damages in an amount adequate to compensate Colibri 2 for Medtronic's infringement of the '739 patent, and in no event less 3 than a reasonable royalty; 4 E. Award Colibri damages in an amount adequate to compensate Colibri 5 for Medtronic's infringement of the '294 patent, and in no event less 6 than a reasonable royalty; 7 F. Award Colibri treble damages in light of Medtronic's willful infringement; 8 9 G. Enter an order finding this to be an exceptional case and award Colibri its reasonable attorneys' fees under 35 U.S.C. § 285; 10 Award Colibri its costs of suit; 11 Н. Enter a permanent injunction against Medtronic and its respective I. 12 13 officers, directors, shareholders, agents, servants, employees, 14 attorneys, all parent, subsidiary and affiliate corporations, their 15 successors in interest and assignees, and all other entities and individuals acting in concert with or on behalf of Medtronic, including 16 17 its distributors, suppliers, and customers, from making, importing, using, offering for sale, and/or selling any product or service falling 18 within the scope of any claims of the '739 patent or otherwise 19 infringing or contributing to, or inducing, infringement of any claim of 20 the '739 patent; 21 22 J. Enter a permanent injunction against Medtronic and its respective 23 officers, directors, shareholders, agents, servants, employees, 24 attorneys, all parent, subsidiary and affiliate corporations, their 25 successors in interest and assignees, and all other entities and 26 individuals acting in concert with or on behalf of Medtronic, including 27 its distributors, suppliers, and customers, from making, importing,

using, offering for sale, and/or selling any product or service falling