



Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 684926

Issued To: Wallaby Medical, Inc

22901 Mill Creek Drive

Laguna Hills California 92653 USA

In respect of:

**Detachment Coil System** 

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-08-30** Date: **2021-05-11** Expiry Date: **2024-05-26** 

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This certificate was issued electronically and is bound by the conditions of the contract.

Gary C Stade





#### **Supplementary Information to CE 684926**

Issued To: Wallaby Medical, Inc

22901 Mill Creek Drive Laguna Hills California

92653 USA

Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
		18 System	The Wallaby Avenir™ Coil System is	
	Wallaby Avenir™	Complex Framing	intended for use in the peripheral and	
	Coil System	Coil	neuro-vasculature to endovascularly	D Water Ser
18CFR06016		6mm x 16cm	obstruct or occlude blood flow in vascular	
	Wallaby Avenir™	18 System	abnormalities of the neurovascular and	
	Coil System	Complex Framing Coil	peripheral vessels.	100
18CFR07019		7mm x 19cm	The Wallaby Avenir™ Coil System is	
	Wallaby Avenir™	18 System	indicated for the endovascular	
	Coil System	Complex Framing	embolization of intracranial aneurysms	
		Coil	and other neurovascular abnormalities,	
18CFR08027		8mm x 27cm	such as arteriovenous malformations and	
	Wallaby Avenir™	18 System	arteriovenous fistulae. The Avenir Coil	
	Coil System	Complex Framing	System is also indicated for arterial and	Class III Implant
		Coil	venous embolization in the peripheral	200
18CFR09030		9mm x 30cm	vasculature.	
	Wallaby Avenir™	18 System		Was I
	Coil System	Complex Framing		
		Coil		
18CFR10034		10mm x 34cm	77 (33) 3	105 / 1
	Wallaby Avenir™	18 System		04. 10
	Coil System	Complex Framing		
		Coil		
18CFR11037		11mm x 37cm		4 m = 10 9
	Wallaby Avenir™	18 System		DSEN
	Coil System	Complex Framing		
		Coil		
18CFR12040		12mm x 40cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
	Wallaby Avenir™	18 System	The Wallaby Avenir™ Coil System is	
	Coil System	Complex Framing	intended for use in the peripheral and	
		Coil	neuro-vasculature to endovascularly	
18CFR13043		13mm x 43cm	obstruct or occlude blood flow in	
	Wallaby Avenir™	18 System	vascular abnormalities of the	
	Coil System	Complex Framing Coil	neurovascular and peripheral vessels.	7169
18CFR14047		14mm x 47cm	The Wallaby Avenir™ Coil System is	
	Wallaby Avenir™	18 System	indicated for the endovascular	
	Coil System	Complex Framing	embolization of intracranial aneurysms	
		Coil	and other neurovascular abnormalities,	
18CFR15050		15mm x 50cm	such as arteriovenous malformations	
	Wallaby Avenir™	18 System	and arteriovenous fistulae. The Avenir	
	Coil System	Complex Framing	Coil System is also indicated for arterial	Class III Implant
		Coil	and venous embolization in the	
18CFR16050		16mm x 50cm	peripheral vasculature.	
	Wallaby Avenir™	18 System		Was II
	Coil System	Complex Framing		
		Coil		
18CFR18050		18mm x 50cm	77 (39) -31	
	Wallaby Avenir™	18 System		15. 10
	Coil System	Complex Framing		
		Coil		
18CFR20050		20mm x 50cm		18 D = -
	Wallaby Avenir™	18 System		SEW
	Coil System	Complex Framing		
		Coil		
18CFR22050		22mm x 50cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
	Wallaby Avenir™	18 System Complex	The Wallaby Avenir™ Coil System is	
18CFR25050	Coil System	Framing Coil 25mm x 50cm	intended for use in the peripheral and neuro-vasculature to endovascularly	
	Wallaby Avenir™	18 System Complex	obstruct or occlude blood flow in vascular	
18CFR25060	Coil System	Framing Coil 25mm x 60cm	abnormalities of the neurovascular and peripheral vessels.	500
10CFR02002	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 2mm x 2cm	The Wallaby Avenir™ Coil System is indicated for the endovascular	Class III Implant
	Wallaby Avenir™	10 System Complex	embolization of intracranial aneurysms	
10CFR02003	Coil System	Framing Coil 2mm x 3cm	and other neurovascular abnormalities, such as arteriovenous malformations and	
	Wallaby Avenir™	10 System Complex	arteriovenous fistulae. The Avenir Coil	
100500000	Coil System	Framing Coil	System is also indicated for arterial and	
10CFR02006		2mm x 6cm	venous embolization in the peripheral	1 0
	Wallaby Avenir™	10 System Complex	vasculature.	
	Coil System	Framing Coil		
10CFR02505		2.5mm x 5cm		

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Device Name	Model, Type	Intended Use per IFU	Classification
Wallaby Avenir™	10 System Complex	The Wallaby Avenir™ Coil System is	
Coii System	3mm x 4cm	neuro-vasculature to endovascularly	K WAS TO THE
Wallaby Avenir™	10 System Complex	obstruct or occlude blood flow in	
Coil System	Framing Coil 3mm x 6cm		160
Wallaby Avenir™	10 System Complex		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Coil System	Framing Coil 3.5mm x 6cm	The Wallaby Avenir™ Coil System is indicated for the endovascular	
Wallaby Avenir™	10 System Complex	embolization of intracranial aneurysms	
Coil System	Framing Coil 4mm x 7cm	such as arteriovenous malformations	Class III Implant
Wallaby Avenir™	10 System Complex	and arteriovenous fistulae. The Avenir	
Coil System		and venous embolization in the	997
Wallaby Avenir™	10 System Complex	peripheral vasculature.	
Coil System	, -	7/ // (	
Wallaby Avenir™			
Coil System	Framing Coil	77 697 79	15 / 11
	5mm x 17cm		100
Wallaby Avenir™	10 System Complex		
Coil System	_		A Q F
	Name  Wallaby Avenir™ Coil System  Wallaby Avenir™ Coil System	Wallaby Avenir™ Coil System  Vallaby Avenir™ Coil System  Vallaby Avenir™ Coil System  Vallaby Avenir™ Coil System Complex Framing Coil Smm x 8cm  Vallaby Avenir™ Coil System Complex Framing Coil Smm x 17cm  Vallaby Avenir™  To System Complex Framing Coil Smm x 17cm  Vallaby Avenir™  Vallaby Avenir™  To System Complex Framing Coil Smm x 17cm	Wallaby Avenir™ Coil System10 System Complex Framing Coil 3mm x 4cmThe Wallaby Avenir™ Coil System is 

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
	Wallaby Avenir™	10 System	The Wallaby Avenir™ Coil System is	
	Coil System	Complex	intended for use in the peripheral and	
		Framing Coil	neuro-vasculature to endovascularly	A WING BOX
10CFR06020		6mm x 20cm	obstruct or occlude blood flow in vascular	
	Wallaby Avenir™	10 System	abnormalities of the neurovascular and	
	Coil System	Complex	peripheral vessels.	1 44
		Framing Coil		
10CFR07013		7mm x 13cm	The Wallaby Avenir™ Coil System is	
	Wallaby Avenir™	10 System	indicated for the endovascular embolization	
	Coil System	Complex	of intracranial aneurysms and other	1
		Framing Coil	neurovascular abnormalities, such as	
10CFR07024		7mm x 24cm	arteriovenous malformations and	
	Wallaby Avenir™	10 System	arteriovenous fistulae. The Avenir Coil	
	Coil System	Complex	System is also indicated for arterial and	Class III Implant
		Framing Coil	venous embolization in the peripheral	200
10CFR08016		8mm x 16cm	vasculature.	
	Wallaby Avenir™	10 System		
	Coil System	Complex		
		Framing Coil		
10CFR08027		8mm x 27cm	77 637 33	65 / 1
	Wallaby Avenir™	10 System		1 / / /
	Coil System	Complex		
		Framing Coil		
10CFR09023		9mm x 23cm		W
	Wallaby Avenir™	10 System		DEL
	Coil System	Complex		
		Framing Coil		
10CFR09030		9mm x 30cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFR10027	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 10mm x 27cm	The Wallaby Avenir <sup>™</sup> Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular	
10CFR10034	Wallaby Avenir™ Coil System	10 System Complex Framing Coil 10mm x 34cm	abnormalities of the neurovascular and peripheral vessels.  The Wallaby Avenir™ Coil System is	70
10HFL03004	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 3mm x 4cm	indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as	Class III Implant
10HFL03006	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 3mm x 6cm	arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial and	Class III Implant
10HFL03008	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 3mm x 8cm	venous embolization in the peripheral vasculature.	
10HFL03010	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 3mm x 10cm		
10HFL04004	Wallaby Avenir™ Coil System	10 System Helical Filling Coils 4mm x 4cm	9-4	

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is intended	
	Avenir™ Coil	Filling Coils	for use in the peripheral and neuro-	
10HFL04006	System	4mm x 6cm	vasculature to endovascularly obstruct or	
	Wallaby	10 System Helical	occlude blood flow in vascular abnormalities	A STATE OF
	Avenir™ Coil	Filling Coils	of the neurovascular and peripheral vessels.	
10HFL04008	System	4mm x 8cm		
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is indicated	
	Avenir™ Coil	Filling Coils	for the endovascular embolization of	
10HFL04010	System	4mm x 10cm	intracranial aneurysms and other	
	Wallaby	10 System Helical	neurovascular abnormalities, such as	Class III Implant
	Avenir™ Coil	Filling Coils	arteriovenous malformations and	Class III Implant
10HFL04015	System	4mm x 15cm	arteriovenous fistulae. The Avenir Coil System	
	Wallaby	10 System Helical	is also indicated for arterial and venous	
	Avenir™ Coil	Filling Coils	embolization in the peripheral vasculature.	
10HFL04020	System	4mm x 20cm		200
	Wallaby	10 System Helical		
	Avenir™ Coil	Filling Coils		Jak 1
10HFL05010	System	5mm x 10cm	II // Valley Yard	
	Wallaby	10 System Helical		
	Avenir™ Coil	Filling Coils	77 (3)	65 /
10HFL05015	System	5mm x 15cm		1. 10

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	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is intended	
	Avenir™ Coil	Filling Coils	for use in the peripheral and neuro-	100
10HFL05020	System	5mm x 20cm	vasculature to endovascularly obstruct or	DANCE POR
	Wallaby	10 System Helical	occlude blood flow in vascular abnormalities	A CONTRACTOR
	Avenir™ Coil	Filling Coils	of the neurovascular and peripheral vessels.	
10HFL06010	System	6mm x 10cm		
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is indicated	
	Avenir™ Coil	Filling Coils	for the endovascular embolization of	
10HFL06015	System	6mm x 15cm	intracranial aneurysms and other	
	Wallaby	10 System Helical	neurovascular abnormalities, such as	Class III Implant
	Avenir™ Coil	Filling Coils	arteriovenous malformations and	Class III Implant
10HFL06020	System	6mm x 20cm	arteriovenous fistulae. The Avenir Coil System	
	Wallaby	10 System Helical	is also indicated for arterial and venous	
	Avenir™ Coil	Filling Coils	embolization in the peripheral vasculature.	7 7 7 7 7 7
10HFL07015	System	7mm x 15cm		200
	Wallaby	10 System Helical		
	Avenir™ Coil	Filling Coils	W // U. W. C.	
10HFL07020	System	7mm x 20cm	11 // Tell 7 Yes	
	Wallaby	10 System Helical		
	Avenir™ Coil	Filling Coils	7//	100
10HFL07030	System	7mm x 30cm		1. 10

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is intended	A ROYALE
	Avenir™ Coil	Filling Coils	for use in the peripheral and neuro-	
10HFL08020	System	8mm x 20cm	vasculature to endovascularly obstruct or	A Line For
	Wallaby	10 System Helical	occlude blood flow in vascular abnormalities	
	Avenir™ Coil	Filling Coils	of the neurovascular and peripheral vessels.	
10HFL08030	System	8mm x 30cm		100
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is indicated	F P 200 1 1 1 5
	Avenir™ Coil	Filling Coils	for the endovascular embolization of	
10HFL09030	System	9mm x 30cm	intracranial aneurysms and other	
	Wallaby	10 System Helical	neurovascular abnormalities, such as	1
	Avenir™ Coil	Filling Coils	arteriovenous malformations and	
10HFL10030	System	10mm x 30cm	arteriovenous fistulae. The Avenir Coil System	Class III Implant
	Wallaby	10 System	is also indicated for arterial and venous	17 January 18
	Avenir™ Coil	Complex Finishing	embolization in the peripheral vasculature.	
	System	Coils		200
10CFN01002	System	1mm x 2cm		
	Wallaby	10 System	77 // 1/ 1/ 1/ 1/ 1/ 1/ 1/ 1/ 1/ 1/ 1/ 1/	
	Avenir™ Coil	Complex Finishing		- 100
	System	Coils		
10CFN01502	3,50011	1.5mm x 2cm	77 (29) 391	62 / 1
	Wallaby	10 System		10
	Avenir™ Coil	Complex Finishing	7 5000	
	System	Coils		
10CFN01503		1.5mm x 3cm	A Comment of the Comm	

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFN01504	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 1.5mm x 4cm	The Wallaby Avenir <sup>™</sup> Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and	
10CFN02002	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2mm x 2cm	peripheral vessels.  The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of intracranial	200
10CFN02003	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2mm x 3cm	aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial	
10CFN02004	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2mm x 4cm	and venous embolization in the peripheral vasculature.	Class III Implant
10CFN02006	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2mm x 6cm		
10CFN02503	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 2.5mm x 3cm		
10CFN02504	Wallaby Avenir™ Coi <b>l</b> System	10 System Complex Finishing Coils 2.5mm x 4cm		SEL

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10CFN03004	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 3mm x 4cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neurovasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities	
10CFN03006	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 3mm x 6cm	of the neurovascular and peripheral vessels.  The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of	
10CFN03008	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 3mm x 8cm	intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System	
10CFN03010	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 3mm x 10cm	is also indicated for arterial and venous embolization in the peripheral vasculature.	Class III Implant
10CFN04006	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 4mm x 6cm	4373	10-1
10CFN04008	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 4mm x 8cm		SEBR
10CFN04010	Wallaby Avenir™ Coil System	10 System Complex Finishing Coils 4mm x 10cm		

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
	Wallaby	10 System	The Wallaby Avenir™ Coil System is intended	
	Avenir™ Coil	Complex Finishing Coils	for use in the peripheral and neuro- vasculature to endovascularly obstruct or	A March
10CFN05008	System	5mm x 8cm	occlude blood flow in vascular abnormalities	16 100
100///05000		10 System	of the neurovascular and peripheral vessels.	
	Wallaby	Complex Finishing		
	Avenir™ Coil	Coils	The Wallaby Avenir <sup>™</sup> Coil System is indicated	
10CFN05010	System	5mm x 10cm	for the endovascular embolization of	THE WAY
	Wallaby	10 System Helical	intracranial aneurysms and other	
	Avenir™ Coil	Finishing Coils	neurovascular abnormalities, such as	
10HFN01002	System	1mm x 2cm	arteriovenous malformations and	Class III Implant
	Wallaby	10 System Helical	arteriovenous fistulae. The Avenir Coil System	Class III Implant
	Avenir™ Coil	Finishing Coils	is also indicated for arterial and venous	200
10HFN01501	System	1.5mm x 1cm	embolization in the peripheral vasculature.	
	Wallaby	10 System Helical		Was III
	Avenir™ Coil	Finishing Coils		
10HFN01502	System	1.5mm x 2cm		
	Wallaby	10 System Helical	77 659 -	
	Avenir™ Coil	Finishing Coils		10
10HFN01503	System	1.5mm x 3cm		
	Wallaby	10 System Helical		
	Avenir™ Coil	Finishing Coils	-07 11 Illinois	1000
10HFN01504	System	1.5mm x 4cm		SEM

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Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is	
10115N01506	Avenir™ Coil	Finishing Coils	intended for use in the peripheral and	The last
10HFN01506	System	1.5mm x 6cm	neuro-vasculature to endovascularly	P 484 30
	Wallaby Avenir™ Coil	10 System Helical	obstruct or occlude blood flow in vascular abnormalities of the neurovascular and	
10HFN02001	System	Finishing Coils 2mm x 1cm	peripheral vessels.	60
201111102002	Wallaby	10 System Helical		
	Avenir™ Ćoil	Finishing Coils	The Wallaby Avenir™ Coil System is	S. CERTO
10HFN02002	System	2mm x 2cm	indicated for the endovascular embolization	
	Wallaby	10 System Helical	of intracranial aneurysms and other	Class III Implant
	Avenir™ Coil	Finishing Coils	neurovascular abnormalities, such as	Class III IIIpiaiii
10HFN02003	System	2mm x 3cm	arteriovenous malformations and	
	Wallaby	10 System Helical	arteriovenous fistulae. The Avenir Coil	
	Avenir™ Coil	Finishing Coils	System is also indicated for arterial and	
10HFN02004	System	2mm x 4cm	venous embolization in the peripheral	100
	Wallaby	10 System Helical	vasculature.	
	Avenir™ Coil	Finishing Coils		
10HFN02006	System	2mm x 6cm		
	Wallaby	10 System Helical		TOTAL S
	Avenir™ Coil	Finishing Coils	7// (20)	62 /1
10HFN02008	System	2mm x 8cm		1 /0

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	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is intended for	
	Avenir™	Finishing Coils	use in the peripheral and neuro-vasculature to	
10HFN02503	Coil System	2.5mm x 3cm	endovascularly obstruct or occlude blood flow in	D WAS SELEC
	Wallaby	10 System Helical	vascular abnormalities of the neurovascular and	
	Avenir™	Finishing Coils	peripheral vessels.	
10HFN02504	Coil System	2.5mm x 4cm		1 4 G/200
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is indicated for	F 1 2 3 5 1 5 1 5 1 5 1 5 1 5 1 5 1 5 1 5 1 5
	Avenir™	Finishing Coils	the endovascular embolization of intracranial	
10HFN02506	Coil System	2.5mm x 6cm	aneurysms and other neurovascular	
	Wallaby	10 System Helical	abnormalities, such as arteriovenous	Class III Implant
	Avenir™	Finishing Coils	malformations and arteriovenous fistulae. The	Class III Implant
10HFN03004	Coil System	3mm x 4cm	Avenir Coil System is also indicated for arterial	
	Wallaby	10 System Helical	and venous embolization in the peripheral	
	Avenir™	Finishing Coils	vasculature.	
10HFN03006	Coil System	3mm x 6cm		200
	Wallaby	10 System Helical		
	Avenir™	Finishing Coils	77 // 12 10 10 10 10 10 10 10 10 10 10 10 10 10	
10HFN03008	Coil System	3mm x 8cm		
	Wallaby	10 System Helical		LESS IN
	Avenir™	Finishing Coils	7// (319) "30	65 / 11
10HFN03010	Coil System	3mm x 10cm		100

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#### **Supplementary Information to CE 684926**

Issued To: Wallaby Medical, Inc

22901 Mill Creek Drive Laguna Hills California

92653 USA

Catalogue Device Number Name		Model, Type	Intended Use per IFU	Classification	
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is intended		
	Avenir™ Coil	Finishing Coils	for use in the peripheral and neuro-		
10HFN03504	System	3.5mm x 4cm	vasculature to endovascularly obstruct or	b What bouse	
	Wallaby	10 System Helical	occlude blood flow in vascular abnormalities		
	Avenir™ Coil	Finishing Coils	of the neurovascular and peripheral vessels.		
10HFN03506	System	3.5mm x 6cm			
	Wallaby	10 System Helical	The Wallaby Avenir™ Coil System is indicated		
	Avenir™ Coil	Finishing Coils	for the endovascular embolization of	CHARLE OF THE A	
10HFN03508	System	3.5mm x 8cm	intracranial aneurysms and other		
	Wallaby	10 System Helical	neurovascular abnormalities, such as	Class III Implant	
	Avenir™ Coil	Finishing Coils	arteriovenous malformations and	Class III Implant	
10HFN04006	System	4mm x 6cm	arteriovenous fistulae. The Avenir Coil System		
	Wallaby	10 System Helical	is also indicated for arterial and venous		
	Avenir™ Coil	Finishing Coils	embolization in the peripheral vasculature.		
10HFN04008	System	4mm x 8cm		24 4	
	Wallaby	10 System Helical			
	Avenir™ Coil	Finishing Coils		Val. III	
10HFN04010	System	4mm x 10cm			
•	Wallaby	10 System Helical			
	Avenir™ Coil	Finishing Coils	77 (89) -90	65 / 11	
10HFN05006	System	5mm x 6cm		3. 10	

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#### **Supplementary Information to CE 684926**

Issued To: Wallaby Medical, Inc 22901 Mill Creek Drive

Laguna Hills California 92653 USA

Catalogue Number	Device Name	Model, Type	Intended Use per IFU	Classification
10HFN05008	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 5mm x 8cm	The Wallaby Avenir™ Coil System is intended for use in the peripheral and neuro-vasculature to endovascularly obstruct or occlude blood flow in vascular abnormalities of the	
10HFN05010	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 5mm x 10cm	neurovascular and peripheral vessels.  The Wallaby Avenir™ Coil System is indicated for the endovascular embolization of	200
10HFN06006	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 6mm x 6cm	intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Avenir Coil System is also indicated for arterial	Class III Implant
10HFN06008	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 6mm x 8cm	and venous embolization in the peripheral vasculature.	
10HFN06010	Wallaby Avenir™ Coil System	10 System Helical Finishing Coils 6mm x 10cm	White the second	

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#### **Supplementary Information to CE 684926**

Issued To:

Wallaby Medical, Inc 22901 Mill Creek Drive Laguna Hills California 92653 USA

# **Certificate History**

Date	Reference Number	Action
30 August 2019	8858411	Initial Issue.
Current	3385412	Change of "Issued to" address to 22901 Mill Creek Drive, Laguna Hills California, 92653, USA.

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