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FDA Grants Market Clearance to Ra Medical Systems for New Peripheral Artery Disease Treatment

Game-Changing DABRA System Removes Blockages from Arteries to Save Limbs and Lives

CARLSBAD, Calif.--(BUSINESS WIRE)-- In an effort to battle Peripheral Artery Disease (PAD), [the leading cause of limb amputations](#), the Food and Drug Administration (FDA) announced today that it has granted market clearance to [Ra Medical Systems](#), makers of excimer lasers and catheters for cardiovascular and dermatological diseases, for the Company's groundbreaking DABRA System. DABRA (Destruction of Arteriosclerotic Blockages by laser Radiation Ablation) changes the paradigm of vascular treatments clinically and economically, continuing the Company's decade-long successful track record of delivering better, safer, faster and less-expensive solutions to treat complex and chronic medical conditions.

[More than 200 million people worldwide](#), including [approximately 8.5 million Americans](#), suffer from [Peripheral Artery Disease](#), a life-threatening condition in which the arteries that carry blood from the heart to the legs and arms narrow and become blocked. [In the United States and Europe, PAD is responsible for approximately 240,000 amputations every year. Nearly one-quarter of these patients die within 30 days and almost half within a year of their limb amputation.](#)

"DABRA's pivotal study demonstrated 95 percent success without any clinically significant adverse events," said Ehtisham Mahmud, MD, study chair and Chief of Cardiovascular Medicine, Director of Sulpizio Cardiovascular Center-Medicine and Director of Interventional Cardiology at the UC San Diego School of Medicine. "Furthermore, the DABRA Catheter is unique in its ability to cross Chronic Total Occlusions (CTOs) without having to cross the lesion with a wire, and it also debulks and modifies arterial blockages, making it an invaluable clinical tool."

Compared to other treatments for arterial blockages, Ra Medical Systems' DABRA has a shorter procedure time and is less expensive. Combined with its safety profile, these DABRA advantages may reduce the costs associated with treating PAD and ultimately lead to greater patient access to, and success with, interventional procedures instead of limb amputation.

"DABRA is what we have been waiting for to better treat our patients," added Athar Ansari, MD, Director of California Heart & Vascular Clinic. "It is a two-in-one. You cross the blockage and remove the plaque from the artery. It is safe, because it stays in the patient's true lumen and does not go subintimal or perforate – common complications of other devices – and it's

effective on all types of lesions. It is revolutionary wireless technology and effective in cases in which other devices have failed. DABRA should be part of every cardiovascular catheter lab's armentarium."

"DABRA's U.S. market clearance is the realization of more than a decade of dedication to the pursuit of delivering a more effective, safer and less expensive way to remove blockages from arteries to save limbs and, ultimately, save lives," concluded Dean Irwin, Ra Medical Systems' Co-Founder and CEO. "To do so, we built Ra Medical Systems and pioneered our cost-effective, small and portable Pharos Excimer Laser for dermatological diseases, thereby creating our company infrastructure and self-funding the development of DABRA. We built our company in a way that no other cardiovascular company has been created, and we will continue delivering groundbreaking catheters, lasers and other devices to treat unmet medical needs in cardiovascular, dermatology and other therapeutic areas of medicine."

About Ra Medical Systems

Ra Medical Systems was founded in 2002 to commercialize excimer lasers and catheters for the treatment of dermatologic and cardiovascular diseases. Its flagship product, Pharos, launched in 2004 and revolutionized the dermatology world with its technology and affordable business model for greater patient access to treatment. Today, Ra Medical Systems continues to make history as it commercializes the DABRA System.

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