



FDA Approves Divine 9[®] with CarraShield™ Personal Lubricant as a Class II Medical Device

Executive Summary

[CarraShield Labs, Inc.](#) announced today the U.S. Food and Drug Administration (FDA) has completed its evaluation of Divine 9[®] personal lubricant made with CarraShield™ and has approved it as a Class II Medical Device. Divine 9 with CarraShield is the first and only personal lubricant formulated with carrageenan, a type of sea algae extract, to be FDA-approved. The official notification can be found on the [FDA website](#).

January 6, 2016, Orlando, Florida – [CarraShield Labs, Inc.](#) announced today the U.S. Food and Drug Administration (FDA) has completed its evaluation of Divine 9[®] personal lubricant made with CarraShield™ and has approved it as a Class II Medical Device. Divine 9 with CarraShield is the first and only personal lubricant formulated with carrageenan to be FDA approved. Carrageenan is a sea algae extract used in many food products and CarraShield Labs has developed a proprietary carrageenan called CarraShield specifically for use in personal lubricants.

In order for a personal lubricant to be marketed and sold in the United States, the FDA now requires all lubricants to have a Class II Medical Device 510(k) clearance. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective as other products already on the market. CarraShield Labs used independent laboratories to show that Divine 9 personal lubricant meets stringent safety and performance standards. Divine 9 with CarraShield successfully completed a complex battery of tests that included:

- Condom compatibility
- Antimicrobial effectiveness
- Microbial presence
- Preservative effectiveness
- Vaginal irritation
- Acute system toxicity
- Cellular toxicity
- Skin sensitivity
- Vaginal irritation
- Osmolality

The [official notification of the approval of Divine 9 with CarraShield](#) can be found on the FDA website.

The FDA has been systematically reviewing all personal lubricants on the market with the intent of requiring products labeled as a “personal lubricant” to obtain a 510(k) status. “With the FDA requirements so strict and the testing process so demanding, we believe many products that call themselves a personal lubricant will soon be off the market,” stated Dean Fresonke, CEO of CarraShield Labs. “While supplying the necessary data was demanding, we knew our naturally-derived products would easily meet the required safety standards.”

About CarraShield Labs, Inc.

CarraShield Labs, Inc., combines nature with science to create products that improve sexual well-being. Intensive research has led to the company’s proprietary, naturally-derived sea algae concentrate called CarraShield™. Divine 9[®] with CarraShield showed promise in blocking the transmission of cancer-causing HPV infection in government-sponsored laboratory studies and is now undergoing human clinical trials at three separate university medical research centers. While the health benefits of CarraShield are being studied, you can enjoy the exotic, sensual feel of Divine 9 today. Look for Divine 9 personal lubricants and other products made with CarraShield in health conscious stores and websites. Learn more at www.carrashieldlabs.com.

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FOR FURTHER INFORMATION, PLEASE CONTACT:

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