

C5 Medical Werks Applies for Clearance, Certification and Licensing for the Global Marketing of ZirDent™ Ceramic CAD/CAM Dental Blocks

Independent assessments worldwide verify safety and quality of technically advanced zirconium oxide material.

May 12, 2008 – Denver, Colorado – C5 Medical Werks, a leading provider of ceramic solutions for the medical device industry, has submitted a 510(k) pre-market notification to the U.S. Food and Drug Administration (FDA) for its new technical ceramic dental component, ZirDent™ CAD/CAM Blocks. ZirDent™ is a zirconium oxide material ideally suited to meet the high aesthetic and physical property needs of the dental market. Additionally, the Company has been assessed recently for the CE certification of ZirDent™ by the British Standards Institute and has also applied to Health Canada for a medical device license for the product.

“Achieving these multiple milestones underscores our dedication to serving unmet needs in the marketplace,” said Brad Coors, President and CEO of C5 Medical Werks.

Contact:

Andrew Nield
Director, Sales and Marketing
2451 River Road
Grand Junction, CO 81505
Tel: +1.303.618-6798
aneild@c5medicalwerks.com

or
Marge D. Hansen
+1.800.443.7602
mhansen@griffsmc.com

An FDA 510(k) pre-market submission must show that a device is substantially equivalent to a legally marketed device, the “predicate.” When equivalency is determined—usually within 90 days—the device is then cleared for marketing in the United States. A CE marking (Conformité Européene) certifies that a product meets the European Union (EU) and European Free Trade Association (EFTA) health, safety and environmental standards for consumer safety. Health Canada requires manufacturers of Class III medical devices to apply for a Medical Device License from the Therapeutics Products Directorate (TPD). ZirDent™ is designated a Class III device in Canada.

About C5 Medical Werks

C5 Medical Werks is a leading provider of ceramic solutions for the medical device industry. The Company manufactures medical grade components with an emphasis on ceramic materials. Based in the United States, the company operates a state-of-the art facility from a single, comprehensive quality system certified to ISO 13485:2003 and complies with all other applicable governmental regulations. Product lines include ceramic implantable components to be used in hip, knee, spine and dental applications, as well as other potential custom implant components. C5 Medical Werks excels at manufacturing premium implantable components that help people live better lives.

C5Medical Werks is located at 2451 River Road, Grand Junction, CO 81505. For more information, please visit www.c5medicalwerks.com or call (877) 259-3757.

###