	Orthogold 100/ Dermagold 100*	Orthogold 100/ Dermagold 100/ Urogold 100*
FDA Device Class	1. Class I, K182682 Therapeutic massager 2. Class II, K191961 Extracorporeal Shock Wave Device for Treatment of Chronic Wounds 3. Class II, K200926 Extracorporeal Shock Wave Device for Treatment of Chronic Wounds	Class I, 510k exempt, FDA product code ISA Electric therapeutic massager
Intended Use	1. The OrthoGold 100 is intended for the activation of connective tissue. 2. The OrthoGold 100™ is indicated to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The OrthoGold 100 is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care. 3. The OrthoGold 100 is indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 years or older). The OrthoGold 100 is indicated for use in conjunction with standard of care burn treatment(s).	Pain Reduction and Improved Blood Supply

WW Approvals(Regions)		

* All devices are the OW100 (OrthoWave)