

## FOR IMMEDIATE RELEASE

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### **Orion Lasers Receives FDA Clearance for Several New Indications for Multi-Application Harmony™ System**

**FORT LAUDERDALE, FL (February 7, 2005)** – Orion Lasers, Inc. announced today that it has received clearance from the U.S. Food and Drug Administration (FDA) to market its Harmony system, an expandable platform for multiple aesthetic laser and light treatments for several new aesthetic and medical applications. Harmony now incorporates, in a single system, up to six discrete technologies (far more than any other platform) for treating countless cutaneous conditions, including skin rejuvenation, permanent hair reduction, several forms of acne, pigmented lesions, scars, striae, vascular lesions, leg veins, vitiligo, psoriasis and tattoos, as well as surgical incision/excision, vaporization, ablation and coagulation of soft tissue. Harmony is also indicated for use on all skin types (Fitzpatrick I-VI) including tanned skin.

#### *Orion Raises the Bar—Again*

For many applications, Harmony offers multiple modalities to ensure every patient can receive the treatment option best suited to their particular condition. In addition to Orion's signature AFT™ broadband light modules, UV module and 1,064-nm Q-switched and long-pulse Nd:YAG laser modules, Harmony now incorporates a 1,320-nm Nd:YAG module and a 2,940-nm Er:YAG module.

*Long-pulse 1,320-nm Nd:YAG:* This popular wavelength is now available on any Harmony system and can be used for the treatment of fine lines and wrinkles, including both periorbital and perioral wrinkles. Additionally, this module can be used for the treatment of mild to moderate inflammatory acne vulgaris, including

back acne. It can also be used for the treatment of atrophic acne scars.

*Long-pulse 2,940-nm Er:YAG:* Also making its debut on the Harmony system is the Erbium YAG laser with its extremely versatile 2,940-nm wavelength used in the treatment of many kinds of soft tissue including skin, cutaneous/subcutaneous tissue, striated/smooth tissue, muscle, cartilage, mucus membranes, lymph vessels/nodes, organs and glands. An incredible number of applications are indicated for this module including, skin resurfacing, many different epidermal pigmented and vascular lesions, keloids, skin tags, scar revision and many more, including lesions specific to many specialties that continue to make in-roads into aesthetic medicine including gynecology, ophthalmology, otorhinolaryngology, podiatry and general medicine.


### *Leading Edge Technology*

Harmony's signature Advanced Fluorescence Technology (AFT™) continues to be the next generation of multi-application pulsed light technology. Its breakthrough design converts unused UV light into the optimal spectrum used by each application. This dramatic boost in efficiency also extends the life of the pulsed light head (up to three times longer than that of other pulsed light systems), significantly lowering the cost of ownership. AFT treatments include moderate inflammatory acne vulgaris, benign pigmented lesions (including dyschromia, hyperpigmentation, melasma and ephelids), cutaneous lesions (including warts, scars and striae), benign vascular lesions (including port wine stains, hemangiomas, telangiectasias, rosacea, etc) and the removal of unwanted hair, including the ability to effect stable long-term or permanent hair reduction.

Harmony's cutting-edge, pulsed UV light source is indicated for the treatment of leukoderma (including vitiligo), as well as psoriasis, atopic dermatitis (eczema) and seborrheic dermatitis.

### *Expanded Indications*

Harmony's original 1064-nm Nd:YAG modules (both Q-switched and long-pulse technologies) have also had their list of indications greatly expanded. In addition to the removing black, blue or green tattoos, effectively treating superficial and deep telangiectasias and reticular veins of the leg (up to 4 mm diameter) and providing a non-ablative treatment of facial wrinkles as part of a skin rejuvenation protocol, Harmony's 1,064-nm wavelength is now also indicated for a much wider range of applications including, treatment and clearance of port wine stains, hemangiomas, warts/verrucae, rosacea, venus lakes, poikiloderma of Civatte, angiomas, scars, striae, psoriasis, lentigos, Café-au-lait macules, seborrheic keratoses, nevi/nevus of Ota, chloasma, skin tags, plaques and the significant reduction black and/or blue/black tattoos.

 long-pulse, 1064-nm module now also includes a new 2-mm spot size that improves the treatment of resistant vessels by focusing the energy more efficiently. Current users can easily add this spot size to their existing system.

Harmony customers have the option of incorporating any or all of the available technologies, whenever it makes sense for their practice. They have the option of starting with as few as one module and allowing their practice to grow financially and in reputation. When they are ready to add a new service, it is as simple as adding a new module, not another system.

“Each upgrade costs far less than another stand-alone system yet provides similar performance,” explains Mauro Wjuniski, CEO of Orion Lasers. “Harmony is the exact system aesthetic practices have been asking for. It absolutely offers the widest range of applications and can be customized to suit the unique needs of a growing diversity of practices. It really is the most affordable way to offer these kinds of aesthetic services.”

## FDA Clears Harmony's Newest Applications

Since 1980, the founders of Orion Lasers have been at the forefront of innovative laser and light-based medical technology. Their rich heritage, technical expertise and intimate understanding of practitioners' needs have inspired the development of Orion's multi-technology/multi-application Harmony system. Orion's mission is to provide modular, cost-effective and high performance designs that enable aesthetic practitioners to confidently offer safe, effective and profitable new services to their patients.

In addition to Harmony, Orion also provides the Sonata diode laser system with proprietary CW Pulse™ Technology—the fastest hair removal treatment in the industry.

Orion Lasers, Inc. is a privately held company headquartered in Fort Lauderdale, Florida. For more information, please go to [www.orionlasers.com](http://www.orionlasers.com).