Radiation-Emitting Products > Laser Facts

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U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Radiation-Emitting Products

Laser Facts

Medical lasers have been used for dermatology applications such as removal of port wine stains, dark spots, tattoos, acne scars and other blemishes for over a decade. Lasers are used for a growing number of cosmetic procedures including hair removal, treatment of wrinkles, and tooth whitening. For risk information on the specific laser treatment that you are considering, ask your physician or operator for the patient labeling for the laser device.

HAIR REMOVAL

The popularity of laser hair removal has increasingly grown, prompting many laser manufacturers to conduct research and seek FDA clearance for their lasers for this indication. The market is growing so quickly that FDA cannot maintain an up-to-date list of all laser manufacturers whose devices have been cleared for hair removal, as this list continues to change. To learn if a specific manufacturer has received FDA clearance, you can check FDA's Website at Medical Device Databases[1] under the 510(k) database. You will need to know the manufacturer or device name of the laser. You can also call FDA's Center for Devices and Radiological Health, Consumer Staff, at 240-276-3103, fax your request to 240-276-3151 or send an e-mail to: DSMICA@cdrh.fda.gov[2].

Manufacturers should be aware that receiving an FDA clearance for general permission to market their devices does not permit them to advertise the lasers for either hair removal or wrinkle treatment, even though hair removal or wrinkle treatment may be a by-product of any cleared laser procedure. Further, manufacturers may not claim that laser hair removal is either painless or permanent unless the FDA determines that there are sufficient data to demonstrate such results. Several manufacturers received FDA permission to claim, "permanent reduction," NOT "permanent removal" for their lasers. This means that although laser treatments with these devices will permanently reduce the total number of body hairs, they will not result in a permanent removal of all hair. The specific claim granted is "intended to effect stable, long-term, or permanent reduction" through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing after a treatment regime, which may include several sessions. The number of hairs regrowing must be stable over time greater than the duration of the complete growth cycle of hair follicles, which varies from four to twelve months according to body location. Permanent hair reduction does not necessarily imply the elimination of all hairs in the treatment area.

FDA does not make comparisons between systems or how well or safely they work compared to another company's system. FDA does not recommend one laser system over another.

Lasers cleared for body hair removal are also cleared for facial hair removal.

- Additional Information on Removing Hair Safely[3]

WRINKLE TREATMENT

Lasers are also being used to treat wrinkles. Several manufacturers have received FDA clearance to claim treatment of wrinkles, while others may claim skin resurfacing. Patients have reported reddening of the skin, which lasted from one to four months. Pain was mild and could be treated with over-the-counter analgesics. Consumers should bear in mind that skin abrasion, whether achieved by lasers, chemicals or abrasive materials, means removing one or more layers of skin, which can be painful and could cause redness, swelling or scarring, depending on how each person heals.

People considering this procedure should consult a dermatologist or the manufacturer to determine whether or not they would be good candidates. Be sure to ask your dermatologist for a copy of the patient labeling for the specific laser device used to understand the risks.

DENTAL TREATMENTS

Several manufacturers have received clearance for argon and carbon dioxide lasers to activate tooth-bleaching solutions and to treat gum disease. Several lasers have clearance for hard tissue use on teeth. On May 7, 1997 FDA cleared the first laser system for treating tooth decay, an erbium YAG laser made by Premier Laser Systems. Recently, American Dental Technologies received FDA clearance to market its laser for caries removal; it is not cleared to remove tooth enamel.

Studies conducted by the manufacturers showed that the laser is as safe and effective as a high-speed drill for removing dental decay and preparing a cavity for a filling. The manufacturer's study indicated that fewer patients needed anesthetic for pain. Any inquiries regarding this method of cavity treatment should be directed to your dentist, who can provide you with patient labeling including risks for the specific laser.

EYE SURGERY

Lasers may be used to remove tissue in eye surgery as well. This may include removing tumors, cataracts, or proliferating blood vessels common to diabetic retinopathy. Several manufacturers have lasers cleared for photorefractive keratectomy (PRK) and Laser-Assisted In Situ Keratomileusis (LASIK), two procedures for correcting nearsightedness, farsightedness, and astigmatism. The laser is used to reshape the cornea and focus images correctly on the retina. For information on eye surgery and which lasers have received clearance, you can access FDA's LASIK Website[4]. As with the other types of patient labeling, be sure to ask the surgeon for the patient labeling for the specific laser device being used.

OTHER MEDICAL USES

Some lasers have been cleared for medical uses such as removing tissue. Because heat from lasers cauterizes blood vessels, there is less bleeding compared to scalpel use. Usually, FDA gives manufacturers general surgical clearances; in order to promote the laser for a specific surgical procedure, manufacturers must first provide FDA with clinical evidence that their lasers are safe and effective for that specific procedure. If you wish to learn whether a specific laser has been cleared for a specific indication, you may contact FDA's Consumer Staff. You will need to provide the name of the manufacturer and the specific product name of the device before contacting the Consumer Staff.

PRACTITIONERS

States regulate who can use lasers for various therapeutic procedures. Medical lasers are prescription devices available for sale only to licensed practitioners. You should check with your state medical licensing board to determine who qualifies as a licensed practitioner in your state.

BIOSTIMULATION LASERS

Biostimulation lasers, also called low level laser therapy (LLLT), cold lasers, soft lasers, or laser acupuncture devices, were cleared for marketing by FDA through the Premarket Notification/510(k) process as adjunctive devices for the temporary relief of pain. These clearances were based on the presentation of clinical data to support such claims. FDA will consider similar applications for these and other claims with the decision to require clinical data being made on an individual basis, taking into consideration both the device and the claim.

LASER RADIATION SAFETY

All laser devices distributed for both human and animal treatment in the U.S. are subject to Mandatory Performance Standards. They must meet the Federal laser product performance standard and must submit an "initial report" to CDRH's Office of Compliance prior to distributing the product (see 21 CFR 1000-1040.11). This performance standard specifies the safety features and labeling that all laser products must have in order to provide adequate safety to users and patients. A laser product manufacturer must certify that each model complies with the standard before introducing the laser into U.S. commerce. This includes distribution for use during clinical investigations prior to device approval.

Certification of a laser product means that each unit has passed a quality assurance test and that it complies with the performance standard. The firm that certifies a laser product assumes responsibility for product reporting, recordkeeping, and notification of defects, noncompliances, and accidental radiation occurrences, as specified in sections 21 CFR 1000-1010. A certifier of a laser product is required to report the product via a Laser Product Report submitted to CDRH. Reporting guides and related regulatory information are available from the Radiation-Emitting Products [5] web site. Distribution of any certified laser products internationally would also require submission of the report.

Links on this page:

1. /MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
2. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfDSMA/consumer-form.cfm
3. /ForConsumers/ConsumerUpdates/ucm048995.htm
4. /MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/default.htm
5. /Radiation-EmittingProducts/default.htm