Birkerød 14. august 2018

Den 30. juli 2018 udsendte FDA i USA en "alert" omhandlende syv amerikanske selskabers kommunikation og markedsføring af "Energy-Based Devices to perform Vaginal Rejuvenation or Vaginal Cosmetic Procedures" til amerikanske patienter og læger. (FDA Alert er vedhæftet).

Forud for den udsendte "alert" har FDA skrevet til syv navngivne firmaer (Alma Lasers, BTL Industries, Venus Concept, Cynosure (Deka distributør i USA), InMode, Sciton, og ThermiGen (ThermiVa), om at besvare spørgsmål relateret til udsagn i deres salgsmateriale og på deres webside. FDA's alert omhandler energy-based devices i bred forstand og dækker både radiofrekvens- og laserudstyr. Ligesom der er tale om flere typer behandlinger, heriblandt "vaginal rejuvenation" og "cosmetic surgery".
Deka (Cynosure) er det ene af i alt to selskaber, som har FDA-godkendelse til gynækologiske behandlinger med laser. Brevet fra FDA går derfor alene på udsagn fra Cynosures webside (kopi af brev fra FDA til Cynosure er vedhæftet).

FDA's skrivelse refererer til en række "adverse events". Jfr. FDA's database er kun tre af disse relateret til Cynosure- og DEKA-udstyr, og de er alle afsluttet som værende lægefejl.

MonaLisa Touch laserudstyret, produceret af DEKA, er FDA-godkendt (K133895 – 2014) dækkende: "*for incision, excision, ablation, vaporization and coagulation of body soft tissue in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, ENT, gynaecology, etc."*
Der er således søgt om godkendelse af en generisk behandlingsform, og derfor ikke på en enkelt lidelse, hvilket er almindelig fremgangsmetode ved FDA-godkendelser.

Den 2. august skrev Hope Riccitti, MD og Editor in Chief, Harvard Women's Health Watch og Associate Professor of Obstetrics, Gynecology, and Reproductive Biology ved Harvard Medical School, en artikel/kommentar til FDA's alert, hvori hun er enig med FDA i, at der skal foretages langtidstudier. Samtidigt kritiserer hun FDA for ikke at være specifikke ang. hvilke behandlinger de bekymrer sig om, da FDA således skaber unødig frygt og misforståelser inden for dokumenterede behandlinger, hvilket igen kan resultere i færre studier i fremtiden (kopi af artikel/kommentar vedhæftet).

**Til information**
Fra Klinik MonaLisa's side vil vi gerne gøre opmærksom på, at vi principielt imødekommer, at FDA udsender en skrivelse, hvori de understreger vigtigheden af klinisk evidens, og at man ikke markedsfører behandlinger herudover.

Klinik MonaLisa i Danmark udfører udelukkende behandlinger af vaginal atrofi med MonaLisa Touch i samarbejde med privatpraktiserende speciallæger i gynækologi og obstetrik. MonaLisa Touch behandlingen er på verdensplan den bedst dokumenterede behandling, med mere end 40 kliniske studier og flere millioner udførte behandlinger.
I Danmark har Hvidovre Hospital udført et pilotstudie, som blev offentliggjort på NFOG i juni 2018. Og professor i gynækologi og obstetrik ved Aarhus Universitetshospital Axel Forman har netop påbegyndt

et randomiseret studie på Herning sygehus, som blandt andet har til formål at afdække langtidseffekter.

Der er således intet i FDA's tiltag, som giver anledning til at ændre MonaLisa Touch-protokollen. Og vi ser derfor heller ikke grund til at ændre på arbejdsgangen i Klinik MonaLisa, hvor patienter som bekendt gennemgår en gynækologisk undersøgelse efterfulgt af en dialog med gynækologen, inden patienten i samråd med gynækologen evt. vælger en MonaLisa Touch behandling.

Klinik MonaLisa udfører hverken kosmetiske eller smertestillende behandlinger i Danmark, men udelukkende behandling af vaginal atrofi. Der er til dato ikke indrapporteret alvorlige bivirkninger af nogen art.

Til orientering vedhæfter vi skrivelser fra hhv. Cynosure og DEKA om FDA's skrivelse.

Med venlig hilsen / Kind regards

Karsten Lund

MonaLisa Nordic Aps
Blokken 11
DK-3460 Birkerød

tel +45 3133 6662
cell +45 2177 4182
web: klinikmonalisa.dk Facebook: /klinikmonalisa

July 24, 2018

Connie Hoy
Official Correspondent
Cynosure, Inc.
5 Carlisle Road
Westford, MA 01886

Document Number: CPT1800139

Dear Ms. Hoy:

It has come to our attention that you may be marketing the DEKA SmartXide$^2$ Laser System (MonaLisa Touch), which meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act (FD&C Act), in a manner that potentially violates the FD&C Act.

Specifically, the DEKA SmartXide$^2$ Laser System (MonaLisa Touch) was cleared (K133895) for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. However, we have conducted a review of our files and are unable to identify an additional Food and Drug Administration (FDA) clearance or approval supporting the use of the claims located http://www.smilemonalisa.com/ such as the following:

- "MonaLisa Touch is the only technology for vaginal and vulvar health with over 18+ published clinical studies."
- "MonaLisa Touch is a simple, safe, and clinically proven laser treatment for the painful symptoms of menopause, including intimacy."
- 'During a treatment, a vaginal probe is inserted into the patient's vagina, and delivers gentle, virtually painless laser energy to the vaginal wall, stimulating a healing response."
- "It penetrates the wall of the vagina, and stimulates cells that are important in creating fluid, improving collagen synthesis."
- "Fibroblasts activate biosynthesis of new collagen and produce main components of ground substance."

Also, the tip of the sterilized applicator that is inserted through the vulva and moved along the vaginal canal in an outward motion, applying the laser in a 360-degree pattern to the vaginal wall, appears to have been modified from the previous cleared device.

We request that you provide us with the following information:

- FDA clearance or approval number for the DEKA SmartXide$^2$ Laser System (MonaLisa Touch) for the additional claims referenced above.

- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the DEKA SmartXide$^2$ Laser System (MonaLisa Touch) for the additional claims referenced above.

In addition, we request that a written response be submitted within 30 days of receipt of this letter. The response and any further correspondence regarding this matter should reference the Document Number, listed above, and should be submitted to:

Complaints Program Manager, WO66-3684
Division of Analysis and Program Operations
Office of Compliance
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, you may contact CDR Cesar Perez at 301-796-5770, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely,

Cesar A. Perez -S

Digitally signed by Cesar A. Perez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Cesar A. Perez -S, 0.9.2342.19200300.100.1.1=2000613874
Date: 2018.07.24 12:42:34 -04'00'

CDR Cesar A. Perez, PhD
Chief
Surveillance and Enforcement Branch I
Division of Premarket and Labeling Compliance
Office of Compliance
Center for Devices and Radiological Health

# FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication

**Date Issued:**

July 30, 2018

**Audience:**

- Patients considering any vaginal "rejuvenation" or cosmetic vaginal procedure, or procedures intended to treat vaginal conditions and symptoms related to menopause, urinary incontinence, or sexual function
- Health care providers who perform vaginal procedures using energy-based devices

**Specialties:**

Primary Care, Obstetrics and Gynecology, Plastic Surgery, General Surgery

**Device:**

Energy-based devices - commonly radiofrequency or laser - that have received FDA clearance for general gynecologic tool indications, including, but not limited to, the destruction of abnormal or pre-cancerous cervical or vaginal tissue and condylomas (genital warts).

**Purpose:**

To alert patients and health care providers that the use of energy-based devices to perform vaginal "rejuvenation," cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events. The safety and effectiveness of energy-based devices for treatment of these conditions has not been established.

**Summary of Problem and Scope:**

We are aware that certain device manufacturers may be marketing their energy-based medical device for vaginal "rejuvenation" and/or cosmetic vaginal procedures. The safety and effectiveness of energy-based medical devices to perform these

procedures has not been established.

Vaginal "rejuvenation" is an ill-defined term; however, it is sometimes used to describe non-surgical procedures intended to treat vaginal symptoms and/or conditions including, but not limited to:

- Vaginal laxity
- Vaginal atrophy, dryness, or itching
- Pain during sexual intercourse
- Pain during urination
- Decreased sexual sensation

To date, we have not cleared or approved for marketing any energy-based devices to treat these symptoms or conditions, or any symptoms related to menopause, urinary incontinence, or sexual function. The treatment of these symptoms or conditions by applying energy-based therapies to the vagina may lead to serious adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain.

**Recommendations for Patients:**

- Be aware that the safety and effectiveness of energy-based devices to perform vaginal "rejuvenation" or cosmetic vaginal procedures has not been established.
- Understand that the FDA has not cleared or approved any energy-based medical device for vaginal "rejuvenation" or vaginal cosmetic procedures, or for the treatment of vaginal symptoms related to menopause, urinary incontinence, or sexual function.
- Discuss the benefits and risks of all available treatment options for vaginal symptoms with your health care provider.
- If you have undergone treatment for vaginal "rejuvenation" and experienced a complication, you are encouraged to file a report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport/ucm085568.htm)**.

**Recommendations for Health Care Providers:**

- Be aware that the safety and effectiveness of energy-based devices to perform vaginal "rejuvenation" or cosmetic vaginal procedures has not been established.
- Understand that the FDA has not cleared or approved any energy-based medical device for vaginal "rejuvenation" or vaginal cosmetic procedures, or for the treatment of vaginal symptoms related to menopause, urinary incontinence, or sexual function.
- Discuss the benefits and risks of all available treatment options for vaginal symptoms with your patients.
- If any patients experience adverse effects from procedures that involved the use of energy-based devices to perform vaginal "rejuvenation", cosmetic procedures, or treat genitourinary symptoms of menopause, sexual dysfunction, or urinary incontinence, please file a report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program (/Safety/MedWatch/HowToReport**

**/ucm085568.htm)**.

**FDA Activities:**

We are aware that certain device manufacturers may be inappropriately marketing their energy-based devices for the uses noted above that are outside of their cleared or approved intended uses. **We have contacted (/MedicalDevices/ResourcesforYou/Industry/ucm111104.htm)** these manufacturers to share our concerns and will be monitoring their claims about uses of their products.

In addition, we will continue to monitor reports of adverse events associated with this issue and will keep the public informed if significant new information becomes available.

**Reporting Problems to the FDA:**

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with procedures marketed as vaginal "rejuvenation". If you experience adverse events associated these procedures, we encourage you to file a voluntary report through **MedWatch (/Safety/MedWatch/default.htm)**, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** should follow the reporting procedures established by their facilities.

**Other Resources:**

- The American College of Obstetricians and Gynecologists Committee Opinion - **Vaginal "Rejuvenation" and Cosmetic Vaginal Procedures (https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Vaginal-Rejuvenation-and-Cosmetic-Vaginal-Procedures)**
- The American College of Obstetricians and Gynecologists Position Statement - **Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance (https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Fractional-Laser-Treatment-of-Vulvovaginal-Atrophy-and-US-Food-and-Drug-Administration-Clearance)**

**Contact Information:**

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

**More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)**

**2018 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm)**

**2017 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)**

# Harvard Health - FDA warning on vaginal laser procedures should emphasize informed choices, not fear

- Harvard Health Blog -
https://www.health.harvard.edu/blog
-

Posted By
Hope Ricciotti, MD
On August 2, 2018 @ 11:02 am In
Health,Menopause,Women's
Health
|
On July 30th, the FDA sent out a stern warning against the use of energy devices (laser therapy) to perform "vaginal rejuvenation," and for procedures to treat symptoms related to sexual function, because of worries about adverse events. I agree with the FDA that these devices need more study, clear indications, informed patients, and skilled and ethical physicians to be used safely.
However, I have concerns that the FDA, in an overabundance of caution, may limit availability of innovative therapies, which when used correctly may benefit women's reproductive health. In addition, press coverage is causing confusion about the different procedures.

Genitourinary syndrome of menopause (GSM)
The North American Menopause Society and International Society for the Study of Women's Sexual Health recently introduced the term genitourinary syndrome of menopause (GSM) to describe the constellation of signs and symptoms associated with decreased estrogen and other hormones at the time of menopause. This syndrome affects approximately 50% of menopausal women and can cause vaginal dryness, itching, irritation, discharge, and painful sex.

Vulvovaginal atrophy often worsens over time when it is not treated, unlike hot flashes that usually go away within a few years. Over 90% of women do not seek treatment for vaginal dryness and painful intercourse because of stigma, embarrassment, or doubt that there are safe therapies to help.
Standard treatments for GSM fall short for some Standard treatment options for vulvovaginal atrophy include nonhormonal vaginal moisturizers and low-dose vaginal estrogen. In addition, maintaining regular intercourse can enhance vaginal health by increasing blood flow. Estrogen helps alleviate symptoms through enhanced lubrication, and improved pelvic muscle tone and elasticity of the vagina.

However, many women do not want to use estrogen or can't (even topically), because while absorption of vaginal estrogen is limited, some hormone exposure can pose a risk. For these women and their doctors, the limited options for effective treatment are frustrating. Vaginal laser therapy appeared to offer a promising nonhormonal option.

Vaginal laser therapy for GSM is not the same as vaginal rejuvenation. Preliminary data suggest that laser technology may offer benefits in treating vulvovaginal atrophy, but we need more data to assess its true safety and effectiveness, particularly over the long term. The FDA's goal to protect women seeking treatment for vulvovaginal atrophy is best served by giving women accurate information about their options. Generally speaking, standard treatments should be tried first until we know more about the long-term risks and benefits of laser procedures. That said, I worry about misunderstanding of the FDA statement shutting down studies (and minds). For some women, laser-based therapies may prove to be a reasonable way to relieve GSM symptoms and improve quality of life.

So what is vaginal rejuvenation, anyway?
Typically, the term "vaginal rejuvenation" applies to procedures that alter the size or shape of the vagina or labia or recreate the hymeneal ring. The goals of these procedures are primarily cosmetic changes, or to enhance sexual satisfaction. Unfortunately, the procedures are not clearly defined. The American College of Obstetricians and Gynecologists defines Harvard Health Blog FDA warning on vaginal laser procedures ...
https://www.health.harvard.edu/blog/fda-warning-on-vaginal-las...

vaginal rejuvenation and cosmetic procedures as "designer vaginoplasty," "revirgination," other cosmetic vaginal procedures, and "G-spot amplification" (injection of collagen into front wall of the vagina). These are elective procedures without a clearly defined medical purpose.

Taking the FDA warning in context
We must not forget that advances in women's health care have been hindered by lack of rigorous studies in women, and by hesitance to openly address women's reproductive and sexual health concerns. (Concerns about erectile dysfunction drugs causing dangerously low blood pressure did not result in warnings against using those drugs altogether.) With this history in mind, the FDA could have crafted this warning more carefully to delineate between the types of procedures, and to encourage further research on how women's bodies respond to such innovations. In addition, off-label use of medications and procedures has often led to FDA approval of new therapies (including, interestingly, the most popular class of erectile dysfunction drugs, which were initially studied as a treatment for high blood pressure and chest pain).

Physicians must provide accurate and current information to patients, who should be fully engaged in the informed decision-making process for all medications and procedures. We should not inflame women's fear of estrogen, and we should give them all options to consider. The FDA should not conflate cosmetic procedures with innovative treatments that may improve quality of life, and it should not engage in fearmongering with regard to women's health and relevant technology.

I welcome the dialogue and hope the FDA will work to allow this technology to continue to be studied by gynecologists, just like it was for dermatologists treating skin conditions.

Related Information:

A Guide to Women's Health: Fifty and forward Article printed from Harvard Health Blog: https://www.health.harvard.edu/blog

URL to article: https://www.health.harvard.edu/blog/fda-warning-on-vaginal-laser-procedures-should-emphasize-informed-choices-not-fear-2018080214405

A Hologic Company

5 Carlisle Road
Westford, MA 01886
www.cynosure.com

t 978 256 4200
t 800 886 2966
f 978 256 6556

August 2, 2018

El.En. SpA
DEKA Srl
Via Baldanzese 17 – 50041
Calenzano – Italy

Dear Sirs,

On July 30, 2018 the FDA issued a statement expressing concerns regarding "vaginal rejuvenation" procedures using energy-based devices and submitted letters to seven companies who manufacture such devices, including Cynosure Inc., a division of Hologic Inc. It is our understanding that the letters received by each company vary in content and concerns as each of the products referenced by FDA have distinct clearances and claims. The letter received by Hologic did not question the safety of the device manufactured by DEKA and distributed by Hologic in the United States but did question some of the claims located on the Hologic website (www.smilemonalisa.com) and whether the existing 510(k) clearances adequately include those claims. As a leader in women's health, Hologic has a strong track record of developing products based on science and clinical evidence as well as meeting our regulatory obligations and so we take the contents of this letter seriously.

As a reminder, the SMARTXIDE2 Laser System (MonaLisa Touch) was cleared on September 5, 2014 by the FDA for indications that include gynaecology applications; specifically, incision, excision, ablation, vaporization, and coagulation of the body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology, gynaecology, neurosurgery, orthopedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery, and genitourinary surgery.

We are evaluating the concerns raised in the letter and we intend to work collaboratively with the agency to respond to their questions. We are committed to marketing our products in compliance with FDA requirements and believe a higher level of scrutiny from regulatory authorities will benefit our customers. Given our strength in women's health, the many studies completed on MLT, and our efforts to demonstrate the clinical value of all our products, we are well-poised to be a leader in this area.

We share the same goals as FDA – clinically strong products that improve patient lives and are marketed responsibly.

If you have additional questions call (844) 365-5060 or email cynosureclinicalsupport@Hologic.com.

Sincerely,

Kevin Thornal
President, Cynosure, Inc.

Florence, August 6th, 2018

Re: FDA vs Vaginal Rejuvenation

Dear Distributor, Valued Customer,

one week has already elapsed since FDA has sent a letter to some Companies, sorting them out from a much wider panel of firms, questioning them for some potential not compliance in their advertisement methods and claims.

We, as DEKA, have preferred to collect all the most important facts, carefully listening to all different opinions (FDA, media, KOLs, etc …), before expressing our opinion, because most of the times it is much better to wait the dust goes down to have a better view of the global scenario.

Facts:

- First: DEKA never received any communication or letter or alert from FDA.

- Second: FDA just sent a request of clarifications to Cynosure, Inc., which is DEKA's distributor in US Territories. In this letter FDA asks to Cynosure to prove that some of their claims and advertisements comply with FDA rules, from a regulatory point of view.

Additionally, FDA didn't question the safety of MonaLisa Touch, at all, but just the not perfect alignment between what it has been advertised by Cynosure, and the related 510(k), which includes, by the way, gynecological intended uses.

FDA just expressed an opinion, not a judgment or any conviction.

- Third: Cynosure, Inc. has given to us some explanations and their opinion on what happened. They have sent to us a letter, on august 2, which is copied just after. Cynosure ensures they'll be able to explain and find an agreement with FDA soon.

Cynosure also confirms that the safety of MLT is not questioned by FDA.

It's important here to remind that Cynosure is on today part of Hologic, Inc., one of the most important (with more than USD 11 billion of Market Capitalization in NASDAQ, as HOLX), and one of the more reputed companies operating in Women's Health Care. As DEKA, we have been always very proud that MLT systems were distributed by such an important Company in the USA, proving once more that MLT's reputation reached the highest levels all over the world.



Via Baldanzese, 17 - 50041 Calenzano - Firenze - Italy - Ph +39 055.88.74.942 - Fax +39 055.88.32.884 - info@dekalaser.com - www.dekalaser.com
Cod. Fisc. e Reg. Imp. FI n. 04190470486 - P. IVA IT04190470486 - R.E.A. di FI 425321 - Reg. A.E.E. IT08020000002393 - N. Mecc. FI 025366 - Capitale Sociale € 40.560,00 i.v.

- Fourth: FDA also issued a press release, where they expressed the opinion that energy based devices should ALL prove their efficacy for so called “vaginal rejuvenation” procedures, because some of them might not be safe.

Please note that out of the various companies addressed by FDA, a few of them did not even have gynecological claims for the US market. We of course respect this FDA opinion and are fully convinced that MLT is not part of this dark side of the “vaginal” world. Cynosure, additionally, never referred to “vaginal rejuvenation” in any of its claims and never used these words.

MLT has been the first device which appeared in the market of surgical gynecology, and there are already thousands of systems fully used all over the world. These systems already accomplished millions of sessions. Sincerely, we do not know about any unhappy doctor and we do not know anybody stating that MLT is not useful for women’s well-being.

We have 34 international official papers published in official science magazines, coming from the USA, from Europe, from Asia, and Oceania. Thus we were really surprised to receive calls from some of you expressing doubts on MLT efficacy and/or safety.

THERE ARE NO DOUBTS: MLT is a very effective and safe system.

We strongly believe that it is a perfect synergic tool for women’s health. For that it is enough to digit MLT in any web research engine, to obtain a list of the thousands of medical centers using MLT, and, among them, some of the most important and reputed Universities, worldwide.

This is not for chance, it is because of the results, and of the extreme confidence of people on MLT.

Fifth: some Media communicated that energy based devices for vaginal rejuvenation had tons of adverse side effects over the last years.

We do not know about other companies. We only do know about the DEKA MLT: nothing.

As you probably are aware of, DEKA is continuously monitoring any complain and any adverse event from all over the world, and these records are public and visible in the FDA website. The only ones existing, in all these years, are less than ten. They were fully examined by our clinicians and Cynosure clinicians, and we concluded that all of them were non-significant or based only on operators’ fault. This means zero consistent adverse event over millions of sessions.

We believe that is impossible to do better than this.

We are fully convinced that MLT is the most effective and the safest procedure for vaginal treatments.

We'll continue to maintain regulatory compliance worldwide, and are fully aligned with FDA in their attempt to clean the dark side of the "vaginal" energy based devices world.

At the very end, only a few companies will survive, and we'll continue to be the leaders.

Mauro Galli

Export Manager

DEKA – Italy

For and on behalf of DEKA