「Ulthera Control Unit」 Its Usage status over the world（As of October, 2019）

The status of the approval Acquirement for the device over the countries	Argentina, Australia, Bosnia-Herzegovina, Brazil, Canada, Colombia, Costa Rica, Egypt, El Salvador, European Union, Guatemala, Hong Kong, Indonesia, Iran, Israel, Jordan, Kazakhstan, Korea, Malaysia, Mexico, Morocco, New Zealand, Nicaragua, Peru, Russia, Saudi Arabia, Singapore, Taiwan, Thailand, Turkey, Ukraine, United Arab Emirates, Uruguay, USA, Venezuela, Vietnam
The list of serious side effects could possibly induce by the usage of the device as noted on its instruction for use. (If None, list the information used when applied to FDA）	Erythema (redness), Edema (swelling), Welting, Pain, Bruising, Nerve Effects, Burns/Scarring, Raised area of edema, Transient Sensory Nerve Effects (as a result of inflammation of the nerve).
Total number of the device delivered over the world.	Over 6000 systems are in use globally
Total number of patients or treatment cases	Over 1,563,552 treatments
The Side effect report (cases that are reported to the MHLW）	No case reported to MHLW
The Manufacturer	Ulthera, Inc. 1840 South Stapley Drive, Suite 200 Mesa, Arizona 85204

Name of the company: Ulthera, Inc.
Signature and date: October 24, 2019

Steven J. Kachelmeyer
Executive Director Regulatory Affairs

1840 S Stapley Drive, Ste 200 | Mesa, AZ 85204 | 480-619-4069 | www.merzusa.com

※日本語訳

機器名	Ulthera Control Unit
機器の欧米各国における承認取得情報	米国、アルゼンチン、オーストラリア、ブラジル、カナダ、コロンビア、EU、グアテマラ、香港、韓国、エジプト、UAE、シンガポール、メキシコ、他世界各国
機器の添付文書に掲載している重大な副作用一覧　（ない場合、FDA など承認取得時の内容）	紅斑、浮腫、痛み、傷跡、ぬれ感、神経への影響、火傷、浮腫部の増強、一過性感覚神経への影響
機器の世界における納入台数	6000 台以上
累計患者数または治療数	治療数 1,563,552 件以上
副作用報告（各国の厚生労働省などに提出しているもの）	なし
製造元	Ulthera, Inc.