

Notice regarding US FDA Medical Device Registration of “Aladuck 405/II”

SBI Pharmaceuticals Co., Ltd. (Head office: Minato-ku, Tokyo; Representative Director & President: Yoshitaka Kitao; hereinafter “SBIP”), a subsidiary company of SBI Holdings, Inc. which conducts research and development pharmaceuticals, etc., utilizing 5-aminolevulinic acid (*) announces today that the medical light source device "Aladuck405/II" (hereafter “Aladuck”) marketed in Japan has been registered as a class II medical device with the U.S. FDA (Food and Drug Administration).

Prior to this, Aladuck has obtained “UL certification”, one of the most recognized safety standards in the US electronics industry. In addition, Aladuck has obtained a conformity certificate “CB Report” by conducting safety tests on the device based on IEC (International Electrotechnical Commission) standards. These certifications have made it possible to obtain overseas certification easily and quickly.

Aladuck is a medical light source device that can be used in various surgical sites, as it can illuminate areas that are difficult to illuminate with conventional microscope light sources, and can be used together with a medical endoscope.

SBIP will strive to fulfill Aladuck's worldwide needs and deliver them to wherever medical sites are needed, both domestically and internationally.



(*) 5-aminolevulinic acid (5-ALA): An amino acid produced in mitochondria. It is an important substance that serves as a functional molecule related to energy production in the form of heme and cytochromes, and its productivity is known to decrease with age. 5-ALA is contained in food such as shochu lees, red wine and Asian ginseng. It is also known as a material forming chloroplasts in plants.

For further information, please contact:

SBI Pharmaceuticals Co., Ltd.: Tel: 03-6229-0095 E-mail: info_ala@sbigroup.co.jp