



saluda MEDICAL

SALUDA MEDICAL PTY LTD
GROUND FLOOR
407 PACIFIC HIGHWAY
ARTARMON NSW 2064
AUSTRALIA
TEL +61 2 8405 8700

Federal Communications Commission
Authorization and Evaluation Division
45 L Street NE
Washington, DC 20554
USA

22 March 2022

Confidentiality Request for FCC ID: 2AYGR-3036
Product Name: Evoke™ External Closed Loop Stimulator; Model Number: ECLS130 (eCLS v3)

To whom it may concern,

Pursuant to Sections 47 CFR 0.457(d)(2) and 0.459 of the Commission's Rules, Saluda Medical Pty. Ltd. hereby request confidential treatment of information accompanying this application as outlined below:

Exhibit Type	Confidentiality type being sought	
Operational Description	<input type="checkbox"/> Short Term	<input checked="" type="checkbox"/> Permanent
Circuit Diagram (RF and System)	<input type="checkbox"/> Short Term	<input checked="" type="checkbox"/> Permanent
BOM	<input type="checkbox"/> Short Term	<input checked="" type="checkbox"/> Permanent
Block Diagram	<input type="checkbox"/> Short Term	<input checked="" type="checkbox"/> Permanent
Tune-Up Procedure	<input type="checkbox"/> Short Term	<input checked="" type="checkbox"/> Permanent
Internal photos	<input type="checkbox"/> Short Term	<input checked="" type="checkbox"/> Permanent
Evoke-Z SCS User Manual	<input checked="" type="checkbox"/> Short Term	<input type="checkbox"/> Permanent
Evoke SCS User Manual	<input checked="" type="checkbox"/> Short Term	<input type="checkbox"/> Permanent
External photos	<input checked="" type="checkbox"/> Short Term	<input type="checkbox"/> Permanent
Test Setup photos	<input checked="" type="checkbox"/> Short Term	<input type="checkbox"/> Permanent

Further justification for permanent confidentiality is provided below.

The above materials contain trade secrets and proprietary information not customarily released to the public. The public disclosure of these materials may be harmful to the applicant and provide unjustified benefits to its competitors.

Permanent Confidentiality:

The applicant requests the exhibits listed above as permanently confidential be withheld from public view due to materials that contain trade secrets and proprietary information not customarily released to the public.

These include:

- 1) Operational Description / Theory of Operation
- 2) Circuit Diagram
- 3) BOM

- 4) Block Diagram
- 5) Tune-Up Procedure
- 6) Internal Photos

Only personnel authorised by Saluda Medical have access to this information. The product is provided to patients after a prescription-only medical procedure. Information regarding internal photos is not released to the public, the product cannot be obtained by the general public. All parties with access to this information are required to sign non-disclosure agreements. As such the internal photos are highly confidential business information and convey trade secrets pertaining to design and manufacturing.

This device is not available to the general public. It is a prescription medical device provided to physicians through a Saluda Medical representative. All physicians and representatives are under nondisclosure agreements with Saluda Medical. The device is attached to surgically implanted leads and is worn on the patient's body for a trial period of approximately seven days. At the end of the trial period, the device is returned to Saluda Medical. The requirement to return devices is specified in the User Manual.

We understand that internal photos are not routinely held confidential. This request is similar to other medical implant manufacturers, who have been afforded permanent confidentiality of internal photos.

Short-Term Confidentiality:

Pursuant to DA04-1705 June 15, 2004 of the Commission's public notice, we also request temporary confidential treatment of information accompanying this application as outlined below for an initial period of 180 days. These include:

- 7) User's Manuals
- 8) External Photos
- 9) Test Setup Photos

This request is in-line with the estimated time to receive clearance to go to market by the FDA (Food and Drug Administration).

Thank you for your consideration. Please do not hesitate to contact the undersigned below if the Commission disagrees with our position or requires further justification.

Sincerely,



Dr. Peter Aigner, Head of Electrical Engineering