Label and Label Location

Naìda CI Q70

Pursuant to paragraph §2.925 of 47 C.F.R. the Advanced Bionics Naida CI behind-the-ear (BTE) sound processor that is used by the cochlear implant to enable hearing, which is subject of this filing, shall bear a permanently affixed, readily visible label listing the information as specified in §2.926 and §15.19(a) of 47 C.F.R.

Due to the specific use of the sound processor (as shown on Figure 1) its external surface is in a permanent contact with the skin behind the ear and the cochlear implant. Therefore, it is not appropriate to permanently affix a label on the outer surface of the device in order to prevent any possible skin irritations. The only possible place where the FCC ID and the serial number of the device can be put is the part in-between the sound processor and the battery cartridge as shown on Figure 2. However, in this case the size of the FCC ID will be smaller than 2 points, which does not satisfy the requirements for "readily visible" label as defined in §2.925(d)(2) and §2.925(g). Furthermore the Naida CI Q70, as a part of the active implantable medical device, complies with the FDA labeling and traceability requirements.

Therefore, due to the very small size of the device and pursuant to paragraph §15.19(a)(5) of 47 C.F.R., the FCC ID and the statement specified in §15.19(a)(3) are placed in the instructions for use (IFU) as shown on Figure 3.
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Figure 1: Naida CI Q70 - device positioning

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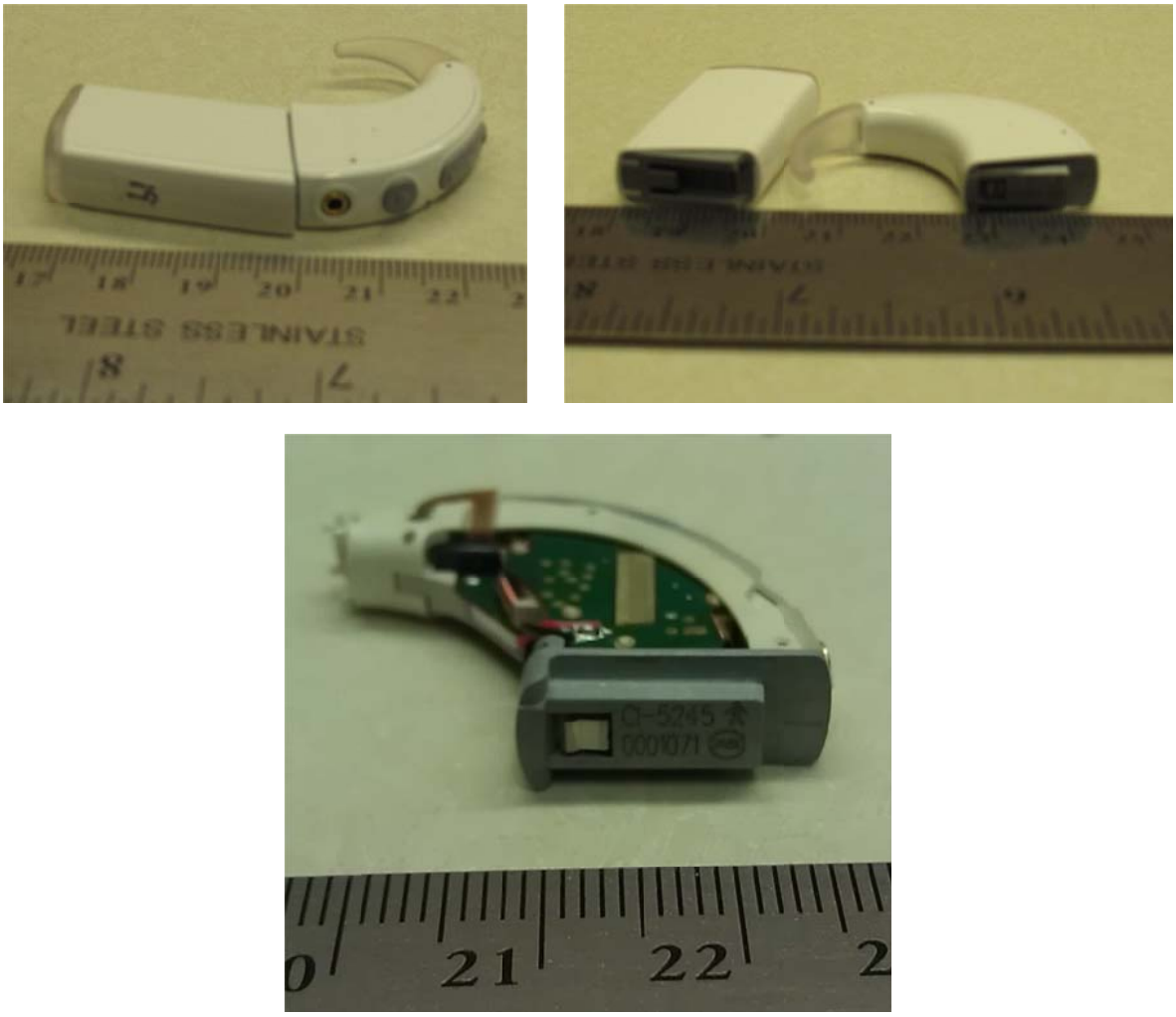

Figure 2: Naida CI Q70 – internal part of the device, device model number and serial number - current size is about 2 points and less.

of the time, 17 indicated they would use it most of the time, and 3 indicated they would use it some of the time. Of the 3 subjects preferring the Control, all indicated they would use ClearVoice some of the time.

ClearVoice is not approved for pediatric use in the United States.

ClearVoice is only available in markets where ClearVoice has received regulatory approval. Contact Advanced Bionics for more information.

This instrument is certified under:

FCC ID: S2B-ABBTE
IC: 10870A-ABBTE

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada. Operation is subject to the following two conditions:
1) this device may not cause harmful interference, and
2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by Advanced Bionics may void the FCC authorization to operate this equipment.

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This Class B digital apparatus complies with Canadian ICES-003.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult your clinic or an experienced radio/TV technician for help

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Figure 3: FCC ID and compliance statement included in the IFU (see pages 27-28)