Date: December 13, 2018

Attention:
Swissmedic, Swiss Agency for Therapeutic Products
Hallerstrasse 7, CH -3012 Bern 7, Switzerland
Email: medical.devices@swissmedic.ch ; materiovigilance@swissmedic.ch

We are writing as a courtesy to provide you with information about a ship and distribution hold and retrieval of certain Pulsante® SPG Microstimulator Systems recently undertaken and concluded by Autonomic Technologies Inc. (ATI) in certain countries in Europe. The issue that prompted the distribution hold and retrieval is not believed to affect the safety of the product. The distribution hold and retrieval was implemented out of an abundance of caution to remedy a deficiency with certification documentation. The details of the issue are explained below.

Details on affected devices:
The Pulsante SPG Microstimulator Systems consists of the Microstimulator (NS-100), a Remote Controller (RC-200), a set of Surgical Tools (SI-110, SI-110, SI-120, LB-100), and a Pulsante Programmer Software (PS-100) that runs on a Standard laptop. A list of the affected serial numbers of the above-mentioned products is provided in **Annex 1**.

Description of the problem:
CE Mark (Annex II) and ISO 13485 certifications of the Pulsante® SPG Microstimulator System was first achieved in February 2012 through UK-based notified body BSI under the then-applicable Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ("Active Implantable Devices Directive"/" AIMDD"). This included certification in respect of:

1. Annex II of AIMDD exclusive of Section 4 - EC Design Certificate
2. Annex II Section 4 of AIMDD - Product EC Design Examination
3. ISO 13485:2003

All three (3) certificates had an expiration date of February 16, 2017. In May 2016, all abovementioned certificates, then current, were successfully transferred to newly appointed France-based notified body GMED. This transfer was well ahead of the expiration date of the certificates.

GMED successfully renewed the Annex II exclusive of Section 4 and ISO (2003) certification prior to their expiration on February 16, 2017.

However, ATI has only recently become aware of the fact that its Product EC Design Examination (Annex II Section 4) renewal process was not completed before expiration of that certificate such that no new valid certificate was issued prior to expiration of the old certificate.

Since becoming aware of the issue, ATI has worked with GMED to attempt to remedy the issue. It was

decided that rather than pursue the expired renewal ATI should pursue a new product EC Design examination certification relevant to the new generation of products only.

To that end, a new product dossier relevant to the new generation system was submitted to GMED on November 8, 2018 and is currently under review. ISO 13485:2016 audits have also been scheduled for January 2019. Based on progress to date on, ATI expects to launch the next generation system in Europe at the beginning of the second quarter of 2019 once CE Mark and ISO 13485: 2016 certification has been achieved. There is no basis to believe these certifications will not be granted.

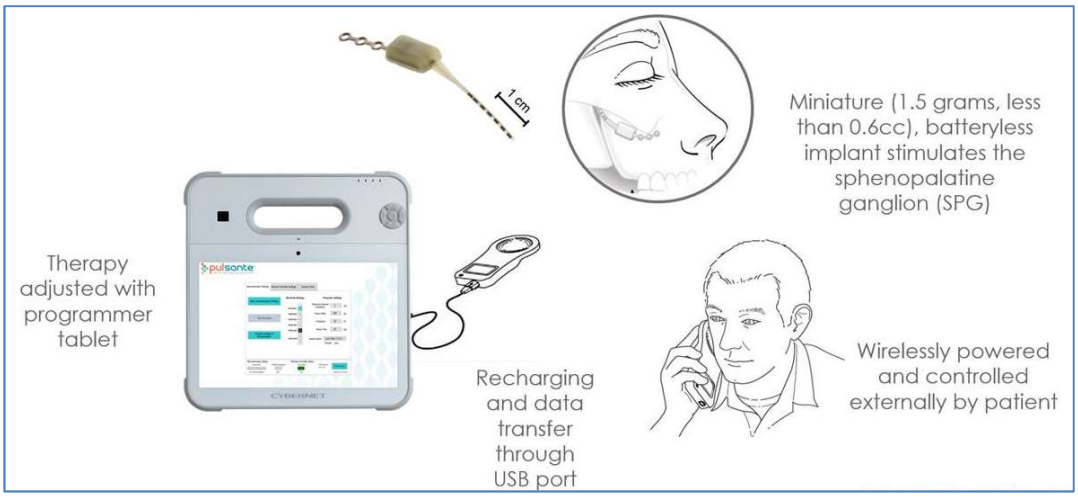
The certification delays outlined above are not associated with a product safety issue. The ship and distribution hold were put in place and a retrieval initiated and completed in certain countries in Europe out of an abundance of caution and to correct the administrative error in respect of the lapsed certifications. The distribution hold will remain in place until the product EC Design examination CE certification process and ISO 13485:2016 are secured in early 2019. After this time ATI will resume shipping of the new generation Pulsante® SPG Microstimulator Systems in Europe.

The relevant Notified Body for the device (GMED) and its respective Competent Authorities (ANSM) both based in France, and ATI's EU Representative (Medpass) and its respective Competent Authority (MHRA) were initially informed of the ship and distribution hold and retrieval initiation. Additional details were provided to ANSM upon request with no further contact. No requests for additional information was received from MHRA.

ATI is notifying through the present correspondence, all additional Competent Authorities in whose countries the product has been distributed. These are:

- Germany
- Finland
- Sweden
- Denmark
- Austria
- Switzerland
- Netherland
- Spain

Introducing the next generation system was the result of a strategic decision based on the timing and availability of the next generation device and the diminishing returns with CE marking and maintaining two versions of the System. The next generation system includes several product improvements based on the cumulative experience with and your feedback on the current system. The next generation system consists of the 1) original Microstimulator (NS-100), an upgraded Remote Controller (RC-300), the original set of Surgical Tools (SI-110, SI-110, LB-100), and a Clinician Programmer (CP-100) that runs on a Medical-Grade Tablet. The next generation device is depicted below.



Action taken by customers:

- As part of the retrieval process undertaken in affected countries in Europe, hospitals which stock the Pulsante® SPG Microstimulator System were asked to identify, quarantine, and return all product to Autonomic Technologies Inc. using a Customer Acknowledgement Form. All lots of all components of the Pulsante® SPG Microstimulator System are included, excluding any Remote Controllers for warranty replacement. All inventory has been accounted for and returned.
- There was no action required for patients who have already been implanted with the Pulsante® SPG Microstimulator System. Autonomic Technologies continues to support these patients as directed by the treating physician and/or hospital (e.g. remote controller replacements, programming, explants).
- For any patients requiring warranty replacement of the Remote Controller, warranty replacements will be issued as required for patients already implanted upon request by the physician/hospital. Hospitals with warranty replacement units of Remote Controllers may continue to hold and use those units as needed.

We will be sure to contact you if there are any material changes to the above information, including progress on the CE certification process and ISO 13485:2016 certification. Please do not hesitate to contact me if you have any questions.

Yours sincerely,

Ziad Rouag
Consultant Vice President, Regulatory and Quality
Direct Dial: +1.415.531.4647
Email: zrouag@ati-spg.com

CC: Rick Gonzalez, ATI Interim CEO