

## Summary of Static and Dynamic Testing per ISO 14801

This summary has **not** been previously reviewed by Health Canada.

### Purpose

The purpose of this test is to establish the static and fatigue strength of the subject dental implants when combined with compatible abutments.

### Methods

The testing was conducted in accordance with ISO 14801, with load to failure in static testing and dynamic loads between 20-200N for 5 million cycles fatigue testing.

The 200N dynamic load has been established based on the clenching forces in the jaw when during mastication per literature on this subject (Stuart et al. Chewing forces in the molar region, Journal of Chewing, vol 23, 2017. Pg 35-39). This force has also been used previously in dynamic testing presented for similar devices licensed by the manufacturer, for example in testing in support of the XYZ Dental Implants (MDL# 159846, App# 254681). Refer to 2.04.04 - Reference and Comparison to Similar and/or Previous Generations of the Device for a comparison of these devices to the subject devices.

5 samples were tested in each test as defined in ISO 14801.

The configuration tested was implants of Ø3mm x 10mm L in combination with 15° standard abutments in length of 8mm. These are considered the worst-case configuration as they are implants of the smallest diameter and the longest length, paired with abutments of maximum angle and length. Finite element analysis has also been conducted on the scope of devices being requested, confirming the worst-case configuration, and is included in Report 123456.

The devices tested are identical to those to be marketed.

The testing has been conducted by the in-house by the manufacturer.

### Acceptance Criteria

Acceptance criteria is defined by previous testing conducted in an identical manner on the comparable, currently licensed, implant/abutment configuration – the ABC Implant system and abutments (MDL# 123456). The ABC Implant configuration tested consisted of Ø3.1mm x 12mm implants paired with a 20° angled abutment in length of 8mm.

Subject configuration	Licensed configuration

Refer to 2.04.04 - Reference and Comparison to Similar and/or Previous Generations of the Device for a comparison of these devices to the subject devices.

## Results

### **Static Testing**

The mean static compressive load achieved by the 5 samples was  $350 \pm 14\text{N}$ .

### **Fatigue Testing**

4 of the 5 samples passed the fatigue testing without any failures.

Review of the documentation found that the 1 failed at 3,354,384 cycles had been assembled using an incorrect set screw and was therefore considered an outlier.

## Discussion and Conclusions

The worst-case subject device was shown to have a similar static strength to the licenced comparator ( $350 \pm 14\text{N}$  vs.  $365 \pm 21\text{N}$ ).

The worst-case subject device met the fatigue strength requirements for this device.