DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 16, 2016

Mr. Jared Crocker
President
Nexus CMF
2825 Cottonwood Parkway Suite 330
Salt Lake City, UT 84121 USA

Re: Postmarket Surveillance Study Number: PS110002/A019
PMA Number: P000023, P000035
Study Requirement Name: Prospective Postmarket Surveillance Study
Filed: March 7, 2011
Amended: March 7, May 11, May 31,June 31,July 28, August 30, 2011, February 21,2012, June 24, September 23, 2013, March 11, April 9, August 25, August 28, September 8, 2014, February 25, 2015

Dear Mr. Crocker:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your section 522 postmarket surveillance (PS) study protocol for the above referenced device. We are pleased to inform you that your PS study protocol is approved. You should begin following this protocol within 30 days of the date of this letter.

Future reports and correspondence pertaining to the data from this PS study protocol should be identified as postmarket surveillance study reports to the above PS reference number. The study start date is the date of this letter. Interim reports describing the progress and current findings of the PS study protocol are due every six months for the first two years and yearly thereafter for the duration of the study.

In addition, any changes to the reporting schedule, the protocol itself, or the protocol's designated contact should be submitted to the address below and identified as a postmarket surveillance study supplement for FDA review and approval prior to being implemented.

Please submit three (3) copies of future reports and other supplements, referencing the PS number above, to:

Cheryl Reynolds
522 Postmarket Surveillance (PS) Studies Program Manager
Food and Drug Administration10903 New Hampshire Ave
WO66-2252
Silver Spring, MD 20993-0002

In lieu of one paper copy, we encourage you to submit an electronic copy as per http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/ucm370879.htm.

Failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the act, 21 U.S.C. 331(q)(1)(C). Further, under section 502(t)(3) of the act, 21 U.S.C. 352(t)(3), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Please note that violations of sections 301(q)(1)(C) or 502(t)(3) may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

Advisory List:

1. Please be advised that your study status will be marked as "Study Pending" on the Postmarket Surveillance 522 webpage www.fda.gov/522studies. This study status is based on the fact that the protocol has been approved, but no subjects have been enrolled.

2. Please be advised that your study status for the Postmarket plan requirements named "TMJ Registry Study Total" and "TMJM Registry Study Partial" are now considered to be closed as they have been replaced by the newly approved study requirements named "Explant Analysis", PS110002/A020 and "Prospective Postmarket Surveillance Study Plan, PS110002/A019.

3. Please be advised that in case that is needed, FDA can write a letter to potential clinical investigators informing them about the importance to participate in the 522 Section Postmarket Surveillance Studies for Nexus CMF TMJ Fossa-Eminence/Condylar Prosthesis System.

If you have any questions regarding this letter, please contact Nicole Jones, Associate Director, Program Operations at 301-796-6062 or at Nicole.jones@fda.hhs.gov.

Sincerely yours,

Nilsa I. Loyo-berrios -S for

Danica Marinac-Dabic, M.D., Ph.D.
Director, Division of Epidemiology
Office of Surveillance and Biometrics
Center for Devices and Radiological Health