K963363

510(k) Summary of Safety and Effectiveness:

NHANES Reference Data Software Option for QDR Series X-Ray Bone Densitometers

Submitter: Hologic, Inc.

Submitter Address: 590 Lincoln Street
Waltham, MA 02154

Contact Person: Nandini Murthy, Regulatory Scientist

Phone Number: (617) 890-2300

Fax Number: (617) 890-8031

Date Prepared: August 23, 1996

Device Trade Name: NHANES Reference Data Software Option for Hologic QDR Series X-Ray Bone Densitometers

Device Common Name: Reference Data for Bone Mineral Densitometer

Device Classification Name: Reference Data for Bone Mineral Densitometer

Predicate Devices: Hologic QDR Series X-Ray Bone Densitometers with Reference Data

Device Description: The NHANES Reference Data Software Option for Hologic QDR Series X-Ray Bone Densitometers provides proximal femur (hip) reference data for male and female Caucasian American, African American, and Mexican American subjects. The new reference data is used in conjunction with previously existing software on QDR Series densitometers, which allows comparisons of patient results to sex, ethnicity, and age matched reference values. The NHANES Reference Data Software Option provides 1) reference data for male and female African American and Mexican American subjects which was previously not available, and 2) the newest, most up to date male and female caucasian American reference data, while maintaining previous Hologic hip reference data, and still allowing clinicians to generate and use local reference data.

The reference values contained in this software option were obtained from published results (A.C. Looker, et al., Osteoporosis International Vol. 5, pg 389-409, 1995) of the National Health and Nutrition Education Survey III ("NHANES III") study, in which 7116 total subjects have been enrolled. Published reference values are stratified by sex, ethnicity, age (from 20 to 80 years), and analysis region (results are tabulated for the Neck, Trochanteric, Intertrochanteric, Ward's, and Total regions of the hip). Standard existing QDR densitometer software was designed to stratify reference values in exactly the

same manner, and thus the published results are directly transferable to the Hologic QDR software.

Patient results for each analysis region can be compared to reference values both graphically and quantitatively. Graphical plots of the age dependent reference Bone Mineral Density (BMD) values corresponding to the sex and ethnicity of the patient are generated, with a marker placed at the position corresponding to the estimated patient BMD and age. Deviation "scores" are computed, quantifying (in population standard deviation units) the difference between the patient's estimated BMD and the mean value for either age matched (Z-score) or young adult (T-score) reference data. In addition, the patient BMD is expressed in percent of the age matched mean and in percent of the young adult mean.

The NHANES caucasian American female reference data differs slightly from the original Hologic data, due to differences in study design (inclusion/exclusion criteria, number of subjects, geographic region and methods of subject recruitment, etc.) and the unavoidable variability between different reference data sets obtained even under the EXACT same conditions. Thus both the Hologic reference data and the NHANES data are equally valid, and the physician may determine which data most accurately reflects the local population. Alternatively the software allows the physician to define and use unique local reference values of their choice.

Intended Use: The intended use of the NHANES Reference Data Software Option for Hologic QDR Series X-Ray Bone Densitometers is to allow comparisons of a subject's estimated proximal femur (hip) Bone Mineral Density (BMD, in g/cm^2) to reference data for sex and ethnicity matched controls. Published results from the NHANES study (A.C. Looker, et al., Osteoporosis International Vol. 5, pg 389-409, 1995), including male and female proximal femur reference values for African American, Mexican American, and caucasian American subjects are included in this software option.

Device Technological Characteristics and Comparison to Predicate Device: Except for the new reference data itself, there are no differences between the NHANES Reference Data Software Option and the previous reference data software and capabilities included in the standard Hologic QDR software.

Conclusion: The NHANES Reference Data Software Option provides a means for the user to compare proximal femur BMD results to reference data for male and female African American and Mexican American subjects, which was previously not available, and provides an additional option for male and female caucasian American reference data. For caucasian American subjects, this software option gives the physician the ability to compare results to standard Hologic reference data, the most recent NHANES reference data (acquired under a different study design), or, as for any subject, to unique user defined local reference data. Patient results are compared graphically and quantitatively to reference values in order to assist the physician in interpretation.