JAN 27 1997

K964685

510(k) Summary

1. Submitter's Information:

John Chatillon & Sons, Inc.
7609 Business Park Drive
Greensboro, NC 27409-9301
Contact - Mr. Joe Troy
1-800-367-0244 Ext. 3120 or (910) 668-0841

2. Classification Name: Dynamometer
Common/Usual Name: Dynamometer
Proprietary Name: Dynamometer - Model CSD200MT

3. Predicate Device:

John Chatillon & Sons, Inc.
Model CSD200 Dynamometer

4. The Chatillon CSD Series Dynamometers are diagnostic devices used for quantitatively evaluating muscle strength. These instruments are powered by a rechargeable battery (7.5 Vdc) which supplies a regulated 5 Vdc excitation voltage to a strain gage load cell. The output from the load cell passes through an A/D converter which produces a digital signal that is directly proportional to the applied force. This signal is then sent to a microprocessor which converts the signal to a force value that is stored in memory and/or displayed on an LCD. This basic design has been used for many years in industrial force measuring instruments that have found their way into hospitals, clinics and other similar facilities through industrial distributors. The instrument submitted herewith is a repackages version of the industrial instrument with attachments that are more appropriate for performing manual muscle testing.

5. This new Chatillon Model CSD200MT Dynamometer is one more diagnostic device to be added to the existing family of similar devices previously approved. The person being tested (patient) is told to push or pull against the instrument using a particular muscle group. The physician/therapist performing the test (operator) resists the push or pull for a predetermined time period. The instrument measures the instantaneous push or pull force produced by the patient and stores the maximum value of the force during a single test in memory. The results of each test must be manually recorded.

6. The predicate device utilizes a load cell as the force measuring element, a printed circuit board to process the signal produced by the load cell and a display (LCD) to indicate the results.

510(k) Summary of Safety and Effectiveness

1. This new Chatillon Model CSD200MT Dynamometer is one more diagnostic device to be added to the existing family of similar devices previously approved. The person being tested (patient) is told to push or pull against the instrument using a particular muscle group. The physician/therapist performing the test (operator) resists the push or pull for a predetermined time period. The instrument measures the instantaneous push or pull force produced by the patient and stores the maximum value of the force during a single test in memory. The operator can then recall the peak push/pull force that occurred during the test using the keypad. The results of each test must be manually recorded.

2. These instruments are powered by a rechargeable battery (7.5 Vdc) which supplies a regulated 5 Vdc excitation voltage to a strain gage load cell. The output from the load cell passes through an A/D converter which produces a digital signal that is directly proportional to the applied force. This signal is then sent to a microprocessor which converts the signal to a force value that is stored in memory and/or displayed on an LCD. This basic design has been used for many years in industrial force measuring instruments that have found their way into hospitals, clinics and other similar facilities through industrial distributors. The instrument submitted herewith is a repackaged version of the industrial instrument with attachments that are more appropriate for performing manual muscle testing.

3. The design accuracy of this instrument is $\pm$ 0.5% of full scale, $\pm$ one least significant count which translates to $\pm$ 0.6 lb.

4. Each individual instrument is calibrated and then checked for accuracy using weights that are checked annually by the State of North Carolina, certified and traceable to N.I.S.T. The instrument is mounted in a test fixture and a 20 lb. weight is applied. Additional 20 lb. weights are applied until the full capacity of the instrument, 100 lb., is reached. This five point calibration ensures the accuracy of the instrument over its full operating range. The unit is then inspected using a different set of weights to verify that the readings do not vary by more than $\pm$ 0.6 lb. at the five calibration points.

Based on the above, the risk of personal injury that could be caused by the use of this instrument is considered negligible. If a patient's threshold of pain is reached, a test can immediately be terminated by the operator without relying on any action but relaxing the resistance applied.

The use of a 7.5 Vdc rechargeable battery as the power source removes any potential for shock or other electrical involvement.

Future developments anticipated for these instruments will only involve the number of test results that can be stored in memory, manipulation of the data within the microprocessor or possibly a change in the physical size and/or shape of the case that encloses the instruments. Any change in the basic technology used in the instruments will be the subject of a separate submittal.